No. 06-

Supreme Court, U.S.
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OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

In Re: TAMOXIFEN CITRATE ANTITRUST LITIGATION

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L. – A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH AND HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Petitioners,

v.

BARR LABS., INC., ASTRAZENCA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Under what circumstances is an agreement by a brand pharmaceutical manufacturer (and patent holder) to share a portion of its future profits with a generic market entrant (and alleged patent infringer), in exchange for the generic's agreement not to market its product, a violation of the antitrust laws?

PARTIES TO THE PROCEEDING

Petitioners, plaintiffs below, are consumers of tamoxifen citrate, third-party payor entities that purchased, paid for, and/or reimbursed for tamoxifen citrate, and a healthcare advocacy group (collectively "Plaintiffs").[1] Respondents, defendants below, are a brand-name pharmaceutical manufacturer, Zeneca, Inc. ("Zeneca"),[2] and a generic pharmaceutical manufacturer, Barr Laboratories, Inc. ("Barr") (collectively "Defendants").

STATEMENT PURSUANT TO RULE 29.6

The only Petitioner in corporate form is Great Lakes Health Plan, Inc. It is an AmeriChoice health plan, a provider of public sector health plans that covers people on Medicaid and other government programs. AmeriChoice is wholly owned by UnitedHealth Group.

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1. The consumer petitioners are: (1) Rebecca Bennish; (2) Maxine Blonstein; (3) Nancy A. Callaway; (4) Helen Donega; (5) Betty Joblove; (6); Karen Jo Koonan; (7) Susan LaCava; (8) Lynn Lovinger; (9) Russella Maloney; (10) Carolene Marks; (11) Carol Platt; (12) Rita Smith; (13) Monica Underwood; (14) Connie Whiteside; and (15) Gail Woollacott. The third-party payor petitioners are : (1) Local 1199 National Benefit Fund for Health and Human Services Employees; (2) Great Lakes Health Plan, Inc.; (3) Allied Services Division Welfare Fund; (4) Patrick J. Lynch as Trustee for the Health and Welfare Fund of the Patrolmen's Benevolent Association of the City of New York and the Retiree Health and Welfare Fund of the Patrolmen's Benevolent Association of the City of New York; (5) IBEW-NECA Local 505 Health & Welfare Plan; (6) A.F. of L. - A.G.C. Building Trades Welfare Fund; (7) Sheet Metal Works Local 441 Health & Welfare Plan; and (8) Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees' Benefit Fund. Petitioner New York Statewide Senior Action Council, Inc. is a New York not-for-profit corporation dedicated to helping its members and other vulnerable populations similarly situated gain access to quality, affordable health care.

2. Successor entities to Zeneca, as a result of a 1999 merger, include AstraZeneca Pharmaceuticals LP and AstraZeneca PLC. Reference herein to "Zeneca" includes, where applicable, predecessor and successor entities, including, Imperial Chemical Industries PLC ("ICI"), Zeneca's former parent which once held the patent for tamoxifen.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDING	ii
STATEMENT PURSUANT TO RULE 29.6	ii
TABLE OF CONTENTS	iii
TABLE OF CITED AUTHORITIES	vi
TABLE OF APPENDICES	xiii
OPINIONS BELOW	1
JURISDICTION	1
STATUTORY PROVISION INVOLVED	1
STATEMENT	1
A. Plaintiffs Have Alleged a Horizontal Market-Allocation Agreement That Violates Federal and State Antitrust Law.	3
B. The Course of the Proceedings and the Disposition in The District Court.	5
C. The Disposition by the Second Circuit.	6

Contents

	Page
REASONS FOR GRANTING THE PETITION ...	6
I. The Standard Adopted By the Second Circuit is In Conflict With Standards Articulated by Other Circuits, the Federal Trade Commission and Scholarly Commentators.	12
II. The Second Circuit's Decision Has Exacerbated Uncertainty and Confusion Surrounding the Propriety of Generic Exclusion Agreements.	15
III. Contrary to the Second Circuit's Opinion, it is a Violation of the Antitrust Laws For Horizontal Competitors To Enter Agreements That Restrict Output, Allocate Markets and Restrain Price Competition, Even When Patents Are Involved.	17
A. The *Noerr-Pennington* Doctrine Does Not Apply to Private Settlements of Litigation.	19
B. The Antitrust Laws Prohibit Unreasonable Restraints of Trade, Including Those That Make Economic Sense for the Participants.	21
C. The Second Circuit Gave Defendants the Benefit of Forced Inferences.	23

Contents

Page

D. The Second Circuit Misconstrued the Hatch-Waxman Act and the Incentives It Provides to Generic Firms. 24

CONCLUSION 27

TABLE OF CITED AUTHORITIES

Page

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In the matter of Abbott Laboratories, et al., No. C-3945, Decision and Order (FTC May 22, 2000), *available at* http://www.ftc.gov/os/2000/05/c3945.do.htm 15

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Andrx Pharm. Corp. v. Elan Corp., 421 F.3d 1227 (11th Cir. 2005) 18

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Page

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Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294 (11th Cir. 2003) 8-9, 13, 14

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Page

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21 U.S.C. § 355(j) 3

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Rule 12 5

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Section 1112 16

Sherman Act/Clayton Act
15 U.S.C. § 1 . . . . . 1, 4

15 U.S.C. § 2 . . . . . 1, 4

15 U.S.C. § 22 5

15 U.S.C. § 26 5

Jurisdictional and Venue Statutes
28 U.S.C. § 1254(1) 1

28 U.S.C. § 1331 5

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Page

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Brief for Henry A. Waxman as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated Sept. 30, 2005) 16

TABLE OF APPENDICES

Page

Appendix A — Opinion Of The United States Court Of Appeals For The Second Circuit Filed August 10, 2006 ..... 1a

Appendix B — Memorandum Of The United States District Court For The Eastern District Of New York Filed May 14, 2003 ..... 70a

Appendix C — Order Of The United States Court Of Appeals For The Second Circuit Denying Petition For Rehearing Filed September 14, 2006 ..... 108a

Appendix D — Dissent From Original Opinion Dated November 2, 2005 ..... 110a

Appendix E — Pertinent Text Of Relevant Statutes 136a

Plaintiffs respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit.

OPINIONS BELOW

The Court of Appeals' August 10, 2006 amended opinion (Pet. App. 1a-69a) is reported at 466 F.3d 187. That opinion amended the court's November 2, 2005 opinion, which is reported at 429 F.3d 370. The September 14, 2006 order of the Court of Appeals denying rehearing and *en banc* rehearing (Pet. App. 108a-109a) is unreported, as is the September 19, 2006 amended order. The opinion of the District Court granting the Defendants' motions to dismiss (Pet. App. 70a-107a) is reported at 277 F. Supp. 2d 121.

JURISDICTION

The judgment of the Court of Appeals was entered on November 2, 2005. An amended judgment was filed on August 10, 2006. A petition for rehearing was denied on September 14, 2006 and an amended order was filed on September 19, 2006. The jurisdiction of this Court rests on 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Relevant portions of the Sherman Act, 15 U.S.C. §§ 1, 2; the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. N. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman Act"); and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003) ("2003 Medicare Amendments") are set out in an appendix to this petition. Pet App. 136a-157a.

STATEMENT

This case involves the same legal issue that was raised in *Federal Trade Commission v. Schering-Plough Corp.*, No. 05-273, __ U.S. __, 126 S. Ct. 2929 (Jun. 26, 2006) (denying

certiorari), as well as three other recent petitions,[3] *i.e.*, the appropriate antitrust standard applicable to an agreement between a brand pharmaceutical manufacturer (and patent holder) and a generic market entrant (and alleged patent infringer) whereby the patent holder shares a portion of its future profits with the alleged infringer in exchange for the latter's agreement to not market its competitive product. The three Circuit Courts of Appeals that have addressed the issue have rendered inconsistent and irreconcilable decisions. In *Schering*, the United States (by the Solicitor General) recognized the importance of the issues raised,[4] but opposed the Federal Trade Commission's ("FTC") petition for certiorari because of factual findings unique to that particular case. *See* Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 12-13. The same important issues are raised in this case without the complications that caused the Solicitor General to oppose certiorari in *Schering*. The radical divergences between the views taken of these issues by the Second, Sixth and Eleventh Circuits, as well as by antitrust enforcement authorities, continues to create enormous uncertainty as to the controlling law, preventing clarity both in antitrust counseling and in the litigation of frequently recurring antitrust issues in the pharmaceutical field.

The Hatch-Waxman Act, 21 U.S.C. § 355, establishes a process to expedite and facilitate the development, approval and marketing of generic drugs. *See Andrx Pharm., Inc. v.*

3. *Andrx Pharm., Inc. v. Biovail Corp.*, 535 U.S. 931 (2002) (No. 01-1050); *Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779); *Valley Drug Co. v. Geneva Pharm., Inc.*, 543 U.S. 939 (2004) (No. 03-1175).

4. "The petition raises important and complex issues concerning the antitrust treatment of settlements in patent cases, particularly settlements that provide for delayed entry into the market combined with 'reverse' payment from the patent holder to the alleged infringer." Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 8.

Biovail Corp., 256 F.3d 799, 801 (D.C. Cir. 2001) ("Congress sought to get generic drugs into the hands of patients at reasonable prices – fast.") (citation omitted). A generic company seeking to market a generic drug must file an Abbreviated New Drug Application ("ANDA") that incorporates the safety and efficacy data developed and previously submitted by the company that produced the original "pioneer" brand-name drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv). If the generic company seeks to enter the market prior to the expiration of patents listed for the pioneer drug, it must include a "Paragraph IV Certification," which is a technical infringement of the patent likely to prompt a patent infringement action. *See* 21 U.S.C. § 355(j)(2)(A)(vii);[5] *see, e.g.*, David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 Food & Drug L. J. 321, 332 (2000). The central purpose of the Hatch-Waxman Act is to encourage generic manufacturers to bring their competing drugs to market. The Act encourages generic manufacturers to file Paragraph IV certifications and to seek market entry prior to the expiration of patents by rewarding the first applicant to do so with an exclusivity period of at least 180 days before the FDA can approve another generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iv) (providing for a 180 day exclusivity period for the first ANDA-IV filer) (the "Exclusivity Period").

A. Plaintiffs Have Alleged a Horizontal Market-Allocation Agreement That Violates Federal and State Antitrust Law.

These antitrust class actions involve the prescription drug tamoxifen citrate ("tamoxifen"), the most essential drug for the treatment of breast cancer. Zeneca manufactures and markets tamoxifen under the brand-name Nolvadex®. Zeneca's former parent, Imperial Chemical Industries PLC ("ICI"), held the patent for tamoxifen, U.S. Patent 4,536,516 (the "'516 Patent"). In 1987, Barr amended its ANDA for tamoxifen to include a

5. An ANDA with a Paragraph IV Certification is referred to herein as an "ANDA-IV."

Paragraph IV Certification, which prompted a patent infringement suit by ICI (Zeneca's parent which was then the patent holder). In 1992, following a bench trial before Judge Vincent L. Broderick, Barr won – the '516 Patent was held invalid and unenforceable. *Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F. Supp. 619 (S.D.N.Y. 1992).

This judgment paved the way for a fully competitive market for generic tamoxifen in which Barr would have had a head-start of at least 180 days. While an appeal from the judgment invalidating the patent was pending in the Federal Circuit, Zeneca and ICI, the patent holders, and Barr, the alleged infringer, agreed to preserve the tamoxifen monopoly and share the monopoly rents. *See Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811, 1993 WL 118931 (Fed. Cir. 1993) (unpublished disposition).[6] Zeneca and ICI agreed to: (1) pay Barr, the alleged infringer, $21 million; (2) pay Barr's supplier $35.9 million; and (3) supply Barr with Zeneca-manufactured tamoxifen for resale in the United States at a high royalty rate. In return, Barr agreed to: (1) abandon its successful challenge of the tamoxifen patent; (2) withdraw its Paragraph IV Certification to manufacture and market generic tamoxifen prior to the patent's expiration; and, if possible, (3) prevent competitive entry by future generic manufacturers.

Among other claims, Plaintiffs allege that the Agreements unlawfully restrained competition in the market for tamoxifen in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and analogous state statutes. While a generic drug is usually priced 30% to 80% below its brand-name counterpart, tamoxifen remained a single-source, monopoly product, with Barr distributing unbranded, Zeneca-manufactured tamoxifen at a price 5% less than branded Nolvadex®. Moreover, when subsequent generic manufacturers sought to enter the tamoxifen

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6. The agreement is embodied in Defendants' March 5, 1993 "Confidential Settlement Agreement" and "Distribution and Supply Agreement" (collectively, the "Agreements").

market, Barr, aided by a court decision rejecting the FDA's "successful defense" requirement, claimed the Exclusivity Period and successfully blocked FDA approval of another generic manufacturer's ANDA (*i.e.*, Mylan Pharmaceuticals, Inc. ("Mylan")).

B. The Course of the Proceedings and the Disposition in The District Court.

In 2000 and 2001, numerous antitrust actions challenging Defendants' Agreements were filed in state and federal courts. For the cases filed in federal court, jurisdiction was premised upon 28 U.S.C. §§ 1331, 1337(a), 15 U.S.C. §§ 22 and 26, and supplemental jurisdiction over Plaintiffs' state law claims was premised on 28 U.S.C. § 1367(a). Defendants removed all of the state court actions to federal court. Pursuant to 28 U.S.C. § 1407, the Judicial Panel on Multidistrict Litigation centralized all of the litigations in the United States District Court for the Eastern District of New York, before the Honorable I. Leo Glasser. *In re Tamoxifen Citrate Antitrust Litig.*, 196 F. Supp. 2d 1371 (J.P.M.L. 2001). On August 26, 2002, the district court denied motions to remand certain actions back to state courts. *In re Tamoxifen Citrate Antitrust Litig.*, 222 F. Supp. 2d 326 (E.D.N.Y. 2002).

On February 14, 2002, Plaintiffs filed their Corrected Consolidated Class Action Complaint ("Complaint"). On May 13, 2003, the district court granted Defendants' motions to dismiss under Rule 12(b)(6), Fed. R. Civ. P., holding that Plaintiffs failed to allege a "bad faith" settlement of the underlying patent infringement litigation. Pet. App. 70a-107a. The district court also held that Plaintiffs failed to allege an antitrust injury because the supra-competitive prices paid necessarily derived from the continued validity of the '516 Patent, despite Barr's successful challenge to the patent at the district court level, and not the Agreements. Final judgment was entered on May 21, 2003, and a timely notice of appeal was filed on June 13, 2003.

C. The Disposition by the Second Circuit.

On November 2, 2005, over a forceful dissent (Pet. App. 110a-135a), the majority of the Second Circuit panel affirmed the dismissal of Plaintiffs' case. An amended opinion was entered on August 10, 2006. Pet. App. 1a-69a. The majority of the Second Circuit panel held that a pharmaceutical patent holder is essentially immune from antitrust liability for paying a generic competitor to abandon even a successful patent challenge and stay out of the market, regardless of: (i) the amount of consideration provided to the generic competitor (even if the consideration grossly exceeds the competitor's expected profits in a competitive market); and (ii) the patent's defects or weakness (short of fraud or complete baselessness), so long as the agreement does not expand the facial scope of the rights that the patent would provide if assumed to be valid and enforceable.

REASONS FOR GRANTING THE PETITION

While Petitioners maintain that the Second Circuit's decision is contrary to settled antitrust law, as addressed further below, review by this Court is necessary to reconcile radically conflicting standards adopted by the Courts of Appeals relative to a matter of vital importance to all Americans, *i.e.*, the escalating cost of prescription drugs. The vast disagreements among the Circuits, on an issue of such basic importance, will continue to cause uncertainty, litigation and delays in generic entry, resulting in billions of dollars in overpayments for pharmaceuticals or, sadly, some consumers' inability to afford needed medication.

Brand-name drugs, many of which claim patent protection, account for most of the increase in drug costs. Generic drugs – chemically and pharmacologically identical but lacking a brand-name – are much less costly, on average about half the price of comparable brand-name drugs. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration; An FTC*

Study 9 (2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf. The Hatch-Waxman Act has been successful in expediting the approval and production of generic drugs. However, its remedial purposes have been thwarted by the type of anticompetitive conduct alleged in this case. When generic versions of popular brand-name drugs are launched, the generics quickly capture the bulk of the market, saving consumers billions of dollars. *See* Federal Trade Commission, *Prepared Statement of the Federal Trade Commission before the Special Committee on Aging of the United States Senate on Barriers to Generic Entry*, July 20, 2006 ("FTC July 2006 Statement"), p. 6[7] ("As a result of price competition, as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, generic sellers typically capture anywhere from 44 to 80 percent of branded sales within the first full year after launch of the lower-priced generic product.") (footnote omitted); *Sanofi-Syntholabo v. Apotex Inc.*, No. 02-2255, 2006 WL 2516486, at *25 (S.D.N.Y. Aug. 31, 2006) (generic version of popular brand-name drug Plavix captured 78.4% of sales within three weeks).

A delay in the launch of a generic version of a popular drug forces consumers to pay millions of dollars *a day* in monopoly rents. Thus, brand-name manufacturers have become adept at abusing the Hatch-Waxman regime to block, frustrate and delay generic entry. When all else fails, brand companies can – and often will – pay cash (or other consideration) to forestall competition.[8] In the end, consumers pay more, not less, as a

7. *Available at:*

http://www.ftc.gov/os/2006 07P052103 Barriers to Generic EntryTestimonySenate07202006.pdf

8. *See, e.g., In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *aff'g* 105 F. Supp. 2d 682 (E.D. Mich. 2000); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp.2d 1279 (S.D. Fla. 2005). Generic companies like respondent Barr can, and often will, accept (Cont'd)

result of the patent challenge originally launched under the provisions of the Hatch-Waxman Act.

> These settlements, which appear to be unique to the pharmaceutical industry, occur when a branded company shares a portion of its future profits with a potential generic entrant in exchange for the generic's agreement not to market is product. Although both the brand company and the generic company are better off financially, these settlements restrict competition at the expense of consumers, whose access to lower-priced generic drugs may be deferred for years.

FTC July 2006 Statement, p. 5-6.

Under the Second Circuit's standard, antitrust review of generic exclusion agreements will be limited to: (1) whether infringement claims based on the patent at issue constitute a "sham" or fraud; and (2) whether the agreement is limited to the facial scope of the patent. The Second Circuit's novel rule is far outside the mainstream of judicial and academic analysis of such agreements. Review under the Sixth and Eleventh Circuit standards require markedly different approaches. The Sixth Circuit considers such agreements *per se* illegal. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003). The Eleventh Circuit applies its own test that inquires into the underlying validity of the patent at the time of the exclusion payment before judging the validity of the reverse payment agreement. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir.

(Cont'd)
cash in lieu of marketing a competing product. In accepting a payment in excess of what it could have made if it had entered the market with its own product, Barr accepted an offer it could not rationally refuse unless restrained by antitrust considerations. In addition to this case, Barr has accepted exclusion payments for ciprofloxacin, *see In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005), and Ovcon 35. *See FTC v. Warner Chilcott Holdings, Inc.*, No. 1:05-cv-021790CKK (D.D.C.).

2003). No other circuit has applied the Second Circuit's approach.

In addition to the inconsistent positions of the Second, Sixth and Eleventh Circuits, the FTC has advanced a "rule of reason" inquiry that does not require direct analysis of the patent merits at all, at least in government enforcement proceedings, but instead focuses on the existence and amount of the reverse payment and other circumstantial factors. *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (FTC Dec. 8, 2003), *rev'd, Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (rejecting the FTC's approach), *cert. denied*, __ U.S. __, 126 S.Ct. 2929 (2006). The United States (through the Solicitor General), has stated that "an appropriate legal standard should take into account the relative likelihood of success of the parties' claims viewed *ex ante*." Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 11.

The Court should accept review of this case to resolve the split in circuit authority. The Court could adopt the standard articulated by one of the circuit courts of appeals or government agencies, or possibly establish another, such as those suggested by antitrust scholars.[9] This case is a particularly appropriate vehicle for addressing conflicting standards. The Second Circuit recognized that "the issues presented have been much litigated and appear to retain their vitality." Pet. App. 2a; *see also* Hemphill, 81 N.Y.U. L. Rev. at 1568:

> "The basic settlement structure is simple, though individual settlements offer many variations on the

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9. *See, e.g.*, C. Scott Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. 1553 (Nov. 2006) ("Hemphill"). There, Professor Hemphill maintains that the FTC, the Eleventh Circuit and the Second Circuit incorrectly analyze these cases in terms of whether the patent or antitrust laws should be accorded primacy, because: (1) the Hatch-Waxman Act established a regulatory regime that trumps the patent law in that particular context; and (2) the issue is how the antitrust laws should be applied under that regulatory regime (not under the patent laws).

> theme. The generic firm abstains from entry, the innovator agrees to pay the generic firm a large sum, typically in the tens or hundreds of millions of dollars, and the parties agree to dismiss the patent suit."

(Footnote omitted). In *Schering*, the United States (by the Solicitor General) recognized the importance of the issue, but opposed the FTC's petition for certiorari because of factual findings unique to that particular case.

> The court of appeals determined that [brand manufacturer] Schering's $60 million payment to [generic manufacturer] Upsher was not compensation for delayed market entry by Upsher, but was instead an independent and bona fide royalty payment by Schering to license Upsher's products. . . . Unless overturned, that determination forecloses any antitrust challenge to the Upsher settlement, *even under the FTC's theory*.

Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 12-13 (emphasis in original); *see also id.* at 15 ("[T]he unusual circumstances surrounding the ESI payment [*i.e.*, payments to another generic manufacturer] suggest that it is unlikely to provide a factual setting conducive to the Court's identification and application of the appropriate legal standard to govern reverse-payment settlements generally.").

In this case, the Court need not afford deference to any factual findings derived from conflicting evidence because, unlike *Schering*, this case was resolved on the face of a pleading by granting a motion to dismiss. The appellate standard of review is *de novo* and the allegations in Plaintiffs' Complaint must be construed in the light most favorable to Plaintiffs. *See, e.g., Allaire Corp. v. Okumus*, 433 F.3d 248, 249-50 (2d Cir. 2006). In addition, courts and commentators have struggled with whether and how to evaluate the patent-holder's likelihood of

success at a patent infringement trial that never occurred because of the exclusion agreement. *Cf. In re Ciprofloxicin Antitrust Litig.*, 363 F. Supp. 2d 514, 531-36 (E.D.N.Y. 2005). Here, however, the patent *was* held invalid, *Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F. Supp. 619 (S.D.N.Y. 1992), and the generic exclusion agreement here was reached while the case was on appeal from that judgment. *Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811, 1993 WL 118931 (Fed. Cir. 1993) (unpublished disposition). Because appellate courts afford deference to factual findings, the range of risks to be evaluated on appeal are narrower than those at trial. *See* Pet. App. 127a-129a (Pooler, J., dissenting).

In counseling against plenary review in *Schering,* the United States (by the Solicitor General) also pointed to the possibility of the potential for eventual review of the *Ciprofloxacin* litigation. Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 16. The Second Circuit's decision here is substantially based upon the reasoning of the district court in *Ciprofloxacin,* 363 F. Supp. 2d at 529-538. *See* Pet. App. 48a-53a.

Accordingly, the facts of this case and the rulings below will allow the Court to address the propriety of generic exclusion/reverse payment agreements under the antitrust laws. Absent guidance by this Court, the conflicting circuit court standards leave everyone – the pharmaceutical industry, antitrust regulators, and the purchasers and consumers of pharmaceuticals (*i.e.*, those who ultimately must pay the bill) – in a quandary. This will continue to cause uncertainty and delays in generic entry, resulting in billions of dollars in overpayments for pharmaceuticals or, sadly, some consumers' inability to afford needed medication.

I. The Standard Adopted By the Second Circuit is In Conflict With Standards Articulated by Other Circuits, the Federal Trade Commission and Scholarly Commentators.

According to the Second Circuit, an agreement between a patent holder and an alleged infringer to settle Hatch-Waxman patent litigation cannot violate the antitrust laws so long as the patent litigation was not a fraud, sham or otherwise baseless and the settlement agreement does not impose restrictions on the alleged infringer that extend beyond the alleged scope of the challenged patent. The Second Circuit's holding is that generic exclusion agreements are beyond the reach of antitrust scrutiny, *per se* legal if you will, even if, as here, the patent holder makes substantial payments to the alleged infringer in exchange for the latter's promise to abandon the patent challenge and its efforts to launch a generic product. The Second Circuit recognized that its rule of *per se* legality shields questionable settlements involving "fatally weak" patents, but concluded that the policy favoring settlement is so strong that it trumps antitrust concerns. Pet. App. 49a ("So long as the law encourages settlement, weak patent cases will likely be settled even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved."). The general preference for settlements must be tempered when settlements have important adverse consequences on third parties. *See* Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 8 ("Although public policy wisely encourages settlements of legal disputes, it does not follow that all settlements are consistent with the public interest.") (citation and quotation marks omitted).[10] The two other circuits that have directly addressed "reverse payment" exclusion agreements have reached radically different conclusions.

The Sixth Circuit, in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), upheld the trial court's summary

10. *See also* Ronald E. Davis, *Reverse Payments Patent Settlements: A View into the Abyss and a Modest Proposal*, Vol. 21, No. 1, ABA Antitrust Journal 26, 32 (Fall 2006) ("The extreme pro-settlement views of the *Tamoxifen* court and others cannot stand.").

judgment ruling that a reverse payment agreement was *per se* illegal. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 683 (E.D. Mich. 2000). "There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade." *Id.* at 908. The substantial "reverse payment" made by the patent holder to the patent challenger was the driving force in the Sixth Circuit's reasoning. "It is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors *by paying the only potential competitor $40 million per year to stay out of the market.*" *Id.* (emphasis added). The Sixth Circuit's decision of *per se* illegality is irreconcilable with the Second Circuit's holding of *per se* legality, which would render issues such as the size of any "reverse payment" made to the patent challenger legally irrelevant.

The Eleventh Circuit, in *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003), reversed a trial court ruling that a "reverse payment" agreement was *per se* illegal. The Eleventh Circuit held that because the "exclusionary power" of the patent needed to be considered, a rule of *per se* liability would be inappropriate "when no court had declared [the brand manufacturer's] patent invalid or unenforceable at the time of the Agreements." *Id.* at 1306 & n.18. From this reasoning, it would follow that a "reverse payment" settlement *is* properly treated as a *per se* antitrust violation when – as in this case – the patent in question *had already been held to be unenforceable* at the time of the challenged agreements. *Valley Drug* held that a fair analysis of the "exclusionary power" of the patent should include such factors as "what lost profits [the brand-name manufacturer] expected from generic competition or what profits [the generics] expected to gain from entry." 344 F.3d at 1310. This is because "the size of the payments might be evidence supporting a claim that the patentee knew that the patent was

procured by fraud, or knew that the patent was invalid, or that there was no objective basis to believe the patent was valid." *Id.* at 1310 n.22. These elements of the *Valley Drug* opinion are irreconcilable with the Second Circuit's key holdings that only a fraudulently procured patent or sham litigation could sufficiently establish weakness of the patent, and that a "reverse payment" of *any* size to the patent challenger is irrelevant.[11] Thus, the amount of the reverse payment could dwarf the profits expected by the generic firm if it succeeded in invalidating the patent and entering the market. Such a payment, held *per se* legal by the Second Circuit, is an offer no rational generic firm could refuse.

Hatch-Waxman Act "reverse payment" agreements have also been a "hot button" issue in antitrust scholarship for years. Academic literature is largely divided between "rule of reason" proponents, on the one hand, and *per se* illegality proponents on the other. No one has argued for *per se* legality, as the dissent points out. Pet. App.123a-126a.[12] Very recently, one of the

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11. The Eleventh Circuit revisited these issues in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), but made clear that it continues to adhere to *Valley Drug*. *Id.* at 1065 ("We are bound by our decision in *Valley Drug*."). The *Schering* opinion also states that although the mere existence of a "reverse payment" is insufficient to establish unlawfulness, "[t]his alone underscores *the need to evaluate the strength of the patent*." *Id.* (emphasis added).

12. Some academic scholars have written that reverse payment settlements of Hatch-Waxman patent litigation with large payoffs to the alleged infringer should be presumptively anti-competitive. *See* Scott C. Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. 1553 (Nov. 2006); Herbert Hovenkamp, *IP and Antitrust*, § 7.4 e2 at 7-38 to 39 (2005 Supp.); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (June 2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391 (2003); Jeremy Bulow, *The Gaming of Pharmaceutical Patents, in 4 Innovation Policy and the Economy*, (Adam B. Jaffe et al. eds. 2004); Mark A. Lemley & Carl Shapiro, (Cont'd)

foremost antitrust commentators has expressed the frank view that the reasoning in *In re Ciprofloxicin Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005), on which the Second Circuit opinion is largely based, just "doesn't work under Hatch-Waxman." Herbert Hovenkamp et al., *IP and Antitrust*, § 7.4 at 7-37 (2006 Supp.).

II. The Second Circuit's Decision Has Exacerbated Uncertainty and Confusion Surrounding the Propriety of Generic Exclusion Agreements.

The Hatch-Waxman Act regime promoting ANDA challenges has resulted in pre-patent expiration generic entry on a number of blockbuster drugs, saving consumers billions of dollars. Of the ten best-selling drugs from 2000, at least four – Paxil, Prilosec, Prozac and Zocor – have faced generic competition prior to patent expiration. *See* Hemphill, 81 N.Y.U. L. Rev. at 1567, n.57; FTC July 2006 Statement, p. 11. Prior to the Second Circuit's decision, FTC enforcement actions[13] and

(Cont'd)

Probabilistic Patents, 19 J. Econ. Perspectives 75 (2005); Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents?* Competition Policy Center Working Paper 05-054 (2005), *available at* http://repositories.cblib.org/iber/cpc/CPC05-54/. Others have argued for application of the rule of reason, Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rav. 747, 779-96 (2002); Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 Antitrust Bull. 491, 534-38 (2002), or for per se illegality. Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 Minn. L. Rev. 1767, 1781-82 (2003).

13. *See, e.g., In the matter of Hoechst Marion Roussel, Inc., et al.*, No. 9293 Decision and Order (FTC May 8, 2001) (regarding Cardizem CD), *available at http://www.ftc.gov/os/2001/05/hoechstdo.htm; In the matter of Abbott Laboratories, et al.*, No. C-3945, Decision and Order (FTC May 22, 2000) (regarding Hytrin), *available at* http://www.ftc.gov/os/2000/05/c3945.do.htm.

private antitrust litigation[14] had virtually eliminated reverse payment settlements in Hatch-Waxman patent litigation. Section 1112 of the 2003 Medicare Amendments, signed by President Bush on December 8, 2003, requires the submission of generic exclusion agreements to the FTC and Department of Justice, though it does not require their advanced approval.[15] Congress passed this law to "re-emphasize the Hatch-Waxman Act's original intent of enhancing competition, not collusion, between generic and name-brand manufacturers." Brief for Henry A. Waxman as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated Sept. 30, 2005) at 10.

For fiscal year 2004, none of the fourteen reported agreements between brand and generic manufacturers contained a payment from the brand to the generic accompanied by deferred generic entry. *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004: A Report by The Bureau of Competition* (Jan. 7, 2005), *available at* http://www.ftc.gov/opa/2005/01/drugsettlement.htm. *http://www.ftc.gov/oos/2005/1/050107medicareactrpt.pdf.* In other words, the parties to Hatch-Waxman patent litigation found ways to settle that did not require paying-off the generic manufacturer. For fiscal 2005, there were sixteen settlements and three included payments to the generic companies to defer market entry. The Eleventh Circuit decision in *Schering,* issued in March 2005 (midway through the fiscal year), had opened that door a crack. On April 24, 2006, FTC Commissioner Jon Leibowitz commented that:

> The more recent evidence – though not complete for fiscal year 2006 – is far more disturbing. In the six months following *Tamoxifen*, more than two-thirds of

14. *See, e.g. In re Cardizem CD Antitrust Litig.*, 218 F.R.D. 508 (E.D. Mich. 2003), *aff'd in part and dismissed on other grounds*, 391 F.3d 812 (6th Cir. 2004).

15. Antitrust regulators could bring action challenging generic exclusion agreements, but application of the Second Circuit is standard would largely immunize such agreements from Antitrust scrutiny.

> approximately ten agreements between brands and generics included payment from the brand and an agreement to defer generic entry. In other words, just before the *Schering* and *Tamoxifen*, there were no payments; just after them, this appears to be the new way to do business.

Jon Leibowitz, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-ack!* (April 24, 2006), *available at* http://www.ftc.gov/speeches/leibowitz/060424 Pharma SpeechACI.pdf; *see also* FTC July 2006 Statement, p. 13-14.

Thus, the Second Circuit's decision has fostered a new era in generic exclusion agreements that keep lower-priced generic drugs *out* of consumers' hands, contrary to the express purposes of the Hatch-Waxman Act. Judge Pooler's dissent – which characterized the majority's "tacit assumption that the settling parties will not act to injure the consumer or competition" as "panglossian" (Pet. App. 125a-126a, n. 37) – has proved prophetic.

III. Contrary to the Second Circuit's Opinion, it is a Violation of the Antitrust Laws For Horizontal Competitors To Enter Agreements That Restrict Output, Allocate Markets and Restrain Price Competition, Even When Patents Are Involved.

Plaintiffs allege that Defendants' Agreements violate the antitrust laws because of a combination of factors, including: (1) the Agreements were entered into after the patent had been held invalid and unenforceable by clear and convincing evidence; (2) the value of the consideration that was provided by Zeneca (the patent holder) to Barr (the alleged infringer) greatly exceeded Barr's litigation costs as well as the expected profits Barr would earn if it entered the market with its own product; and (3) the continuing nature of Defendants' relationship had a continuing adverse effect on other generic manufacturers' efforts to enter the market. Private settlement of patent infringement litigation cannot be deemed an antitrust

safe-haven for horizontal competitors to enter into sweeping output restriction, market allocation and price-fixing agreements. It is well-settled that even holders of valid patents are liable for antitrust violations when they combine with horizontal competitors to exclude competition. *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) ("[P]ossession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of its patent monopoly."); *Andrx*, 256 F.3d at 813 n.15 ("[E]ven a patent-right holder is not immune from antitrust liability."). While it is lawful for patents to be used to protect monopolies, it is not lawful for monopolies to be used to protect patents, which is what the Second Circuit's decision allows.

With the notable exception of the lower courts' decisions here, virtually every court to consider such alleged generic exclusion agreements has, at a minimum, held that plaintiffs stated a claim upon which relief can be granted. *See, e.g., In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (interlocutory appeal upholding the district court's denial of motions to dismiss antitrust claims, and upholding partial summary judgment that agreement was *per se* illegal), *aff'g*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) (motion to dismiss ruling) and 105 F. Supp. 2d 682 (E.D. Mich. 2000) (partial summary judgment ruling); *Andrx Pharm., Inc. v. Biovail Corp.*, 256 F.3d 799 (D.D.C. 2001) (vacating dismissal with prejudice and remanding); *Andrx Pharm. Corp. v. Elan Corp.*, 421 F.3d 1227, 1236 (11th Cir. 2005) (agreement between brand and generic manufacturer stated claim for antitrust violation); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005) (granting motion for partial summary judgment that agreement was *per se* illegal); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003) (granting in part and denying in part motions to dismiss), *but see* 363 F. Supp. 2d 514 (E.D.N.Y. 2005) (granting defendants' motion for summary judgment); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (granting in part and denying in part motions to dismiss).

The Second Circuit did not dispute that Plaintiffs suffered an "injury," but rather, like the district court, held that there was no *antitrust* injury because there was a *lawful* monopoly. *See* Pet. App. 62a ("The Agreement is no doubt 'anticompetitive' the plaintiffs need no additional proof of that. It limited competition between generic tamoxifen and Zeneca's branded product. But, as we have seen, because it did not exceed the scope of the tamoxifen patent, it was not an *unlawful* anticompetitive agreement.") (emphasis in original). Under the Second Circuit's standard, those who improperly acquire patents on drugs will have carte blanche to spend unlimited amounts for the purpose of "buying off" competitors who challenge those patents. In other words, the antitrust laws are completely neutered when pharmaceutical patentees maintain their monopolies through the depth of their pockets, rather than the strength of their patents.

From a legal standpoint, the dissent rightly states that the majority opinion "is not soundly grounded in Supreme Court precedent and is insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws." Pet. App. 117a. The majority opinion embodies "several subsidiary holdings, conclusions, or assumptions." *Id.* Many errors in them are catalogued *seriatim* in the thoughtful dissent. Pet. App.110a-135a. Without belaboring points made in the dissent, we address below just some of the defects in the Second Circuit's opinion.

A. The *Noerr-Pennington* Doctrine Does Not Apply to Private Settlements of Litigation.

The Second Circuit held that unless the monopoly is extended beyond the patent's alleged scope, a "reverse payment" agreement is actionable only if there is fraud or sham litigation. The Second Circuit thus borrows, as a key element of its standard for "reverse payment" cases, a "fraud or sham" doctrine designed instead to define exceptions to immunity for petitioning under the *Noerr-Pennington* doctrine. *Eastern R.R. Presidents'*

Conference v. Noerr Motor Freight Inc., 365 U.S. 127 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965). The dissent rightly states that it is "ill-advised," and at odds with Supreme Court law, to "import" those doctrines from government petitioning activity protected by the First Amendment into an inapposite context. Pet. App. 119a. The majority's rationale for this "importation" is that if the patent litigation "is neither a sham nor otherwise baseless, the patent holder is seeking . . . to protect that to which it is presumably entitled" – referring to the presumption of validity, 35 U.S.C. § 282. Pet. App. 43a & n.22.

But "[t]he presumption, like all legal presumptions, is a procedural device, not substantive law." *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985) (citation omitted). A statute setting rules of procedure and assigning burdens to litigants does not "acquire an independent evidentiary role in any proceeding." *Id.* Thus, a patent does not confer a legal right certain. Rather, it reflects an initial judgment by the Patent and Trademark Office – made after only cursory scrutiny – that an invention is patentable. When a patent is asserted in litigation, accused infringers need not prove that it was acquired by fraud or show that it was a "sham" in order to rebut the presumption of validity; they need only demonstrate that the patent should not have been issued. Virtually every accused infringer asserts invalidity, and nearly half of all litigated patents are ultimately found invalid. *See* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 29 Am. Intell. Prop. L. Ass'n, Q.J. 185 (1998) (studying all patent litigation over an 8 year period and finding that 46% of all patents litigated to judgment were held invalid).

The Second Circuit's ruling essentially allows the patent holder, through the payment of huge sums to alleged infringers, to convert the *rebuttable* (and often rebutted) presumption of patent validity into, for all practical purposes, an *irrebuttable* presumption. The majority thus gave the presumption of validity

improper substantive force, especially where, as here, the presumption *had been rebutted* at the time of the Agreements. The ramifications are especially dire for Hatch-Waxman patent litigation, where generic manufacturers other than the first ANDA-IV filer are likely to be years behind in product development and less financially motivated. *See § III.D. infra.*

Nothing in patent law justifies the resulting safe harbor for weak and defective patents. If instead of fraud or "sham," all that should be required is that the patent be defective, then even if the finding of invalidity that existed at the time of settlement is not dispositive, Plaintiffs should have their own opportunity to show the weaknesses of the patent and the unreasonable restraint of trade resulting from the challenged Agreements. As the dissent points out,

> Both the majority opinion in *Standard Oil* and the concurrence in *Singer* suggest that an antitrust court must go beyond deciding that a lawsuit was not a sham, that is objectively baseless, before it can dismiss an antitrust challenge to the lawsuit's settlement—as opposed to the initiation of the lawsuit—and, in fact, must consider the strength of the patent.

Pet. App. 120a (citing *Standard Oil Co. v. United States*, 283 U.S. 163, 180 (1931); *Singer Mfg. Co.*, 374 U.S. at 197 (White, J. concurring)).

B. The Antitrust Laws Prohibit Unreasonable Restraints of Trade, Including Those That Make Economic Sense for the Participants.

The Second Circuit inexplicably rejected Plaintiffs' antitrust claims largely because it can "make economic sense" to both the patent holder to make, and the generic challenger to accept, a large "reverse payment" to stay out of the market. Pet. App. 44a & n.24. But price-fixing agreements and other conduct prohibited by antitrust laws almost always "make

economic sense" to the participants. The antitrust laws are not designed to protect market participants from doing foolish things that are against their *own* interests. Instead, they prohibit conduct that is in *the participants'* economic self-interest, but that is contrary to the *public's* rightful interest in a competitive market. This aspect of the majority opinion misapprehends a basic point of antitrust economics: price-fixing agreements and other anticompetitive schemes can increase profits to *all* participants because they are at the expense *of the purchasers*, who foot an increased bill which the wrongdoers divide among themselves. *See also* FTC July 2006 Statement, p. 11-12

> "[I]t typically will be more profitable for both parties if the brand-name manufacturer pays the generic manufacturer to settle the patent dispute and agree to defer entry. Although both the brand-name company and the generic company are better off with the settlement, consumers lose the possibility of an earlier generic entry, either because the generic company would have prevailed in the lawsuit or the parties would have negotiated a settlement with an earlier entry date but no payment. Instead, consumers are left with the guarantee of delayed generic entry and paying higher prices."

The Second Circuit's legal basis for inferring lawfulness from mutual profitability is unclear. Perhaps it was drawn from law concerning the "plus factor" of common motive, which holds that conspiracy may be inferred from consciously parallel conduct when, in the absence of a conspiracy, the challenged conduct would present "risk of a substantial loss of" business or goodwill, but "with it there was the prospect of increased profits." *Interstate Circuit, Inc. v. United States*, 306 U.S. 208, 222 (1939). This is referred to as the doctrine of "action against self-interest." *See* VI Phillip E. Areeda, *Antitrust Law*, ¶ 1434c at 243-44 (1986). But it would make a train wreck of antitrust law to hold that conduct that is in the conspiring parties' interests

when an agreement among them exists is not "suspicious" (Pet. App. 42a-43a) and is therefore lawful. The most naked price-fixing would be not "suspicious," and ergo would be lawful, under that ill-conceived legal standard.

C. The Second Circuit Gave Defendants the Benefit of Forced Inferences

The majority tendentiously transmutes plain proof of patent weakness – the patent having being held invalid at the time of the Agreements – into the happy bromide that the patent holder "had sufficient confidence in its patent to proceed to trial." Pet. App. 35a, 47a. But other than settlements entailing large sacrifices of revenue, the patent holder had no viable *alternative* to a trial. Meanwhile, as the dissent points out, the majority finds later victories in defending the patent to be issue-preclusive, even while irreconcilably claiming to honor the longstanding antitrust rule that a challenged agreement must be evaluated based on facts existing when it was made. Pet. App. 34a, n.17, 130a-131a.

Indeed, the Second Circuit's standard would insulate patent holders from antitrust liability in virtually every circumstance. The outcome of trial can only be a win or a loss and the patent holder is protected by both, *i.e.* the patent is either valid, or invalid despite the patent holders "confidence" in going to trial. Notwithstanding the effect of such circular reasoning in this case, the consequences of the Second Circuit's decision are more problematic when weak patents are at stake, since the holders of such patents (who may not have the "confidence" to go to trial) are free to spend monopoly rents on lucrative payments that, economically speaking, cannot rationally be refused by generic competitors. The challenger may receive more money than would have been the case had its challenge succeeded, while the patent holder continues to enjoy monopoly profits, albeit in reduced amounts. The only ones to suffer are the purchasers of the drug. *See* FTC July 2006 Statement, p. 11-12.

D. The Second Circuit Misconstrued the Hatch-Waxman Act and the Incentives It Provides to Generic Firms.

A distressing aspect of the Second Circuit's decision is its assumption that later suits by other patent challengers will be a panacea for anticompetitive effects of "reverse payment" agreements. *See* Pet. App. 50a ("The point will come when there are simply no monopoly profits with which to pay the new generic challengers."). The Second Circuit's (and district court's) contention that settlement with the first ANDA-IV filer simply "clears the field" – implying that a more willing challenger will immediately assume the challenge – defies reality. As the dissent aptly observes, "[t]his position ignores the time gap between" a "reverse payment" settlement and the resolution of such subsequent generic challenges. Pet. App. 121a, n.35.

> A firm must file an ANDA-IV to be eligible for a settlement. The ANDA-IV contains a demonstration by the generic firm that its proposed product is bioequivalent to the innovator's drug, and the firm is capable of making the proposed product. The challenge process requires a detailed description of the basis for belief of invalidity or noninfringement for each of the relevant patents of the innovator. To be a credible threat to the innovator, a generic firm must undertake theses expenses (one generic firm cannot free-ride on another's showing of bioequivalence) and be prepared to see the suit to a conclusion. The number of firms capable of such action is limited.

Hemphill, 81 N.Y.U. L. Rev. at 1582 (footnotes omitted).

The Second Circuit also misconstrued the purpose and effect of the 180 day Exclusivity Period to the first generic manufacturer who challenges the pioneer manufacturer's patent. 21 U.S.C. § 355(j)(5)(B)(iv). The Exclusivity Period is extremely profitable, as it allows the generic manufacturer to

charge supracompetitive prices (only slightly less than the brand). This "head start" also gives the first filer an advantage over subsequent ANDA filers in securing long-term contracts with customers that extend beyond the Exclusivity Period.

> Generic firms other than the first filer will be behind in the approval process, if they have bothered to file at all; they will also be less motivated to initiate or vigorously pursue the challenge. The subsequent filers' return on a challenge, aside from being smaller, depends upon the outcome of the first filers' suit (and possible settlement), providing a strategic motivation to go slow until the uncertainty is reduced. It is therefore inaccurate to assert, as some cases have, that "[i]n a reverse payment case, the settlement leaves the competitive situation unchanged from before the defendant tried to enter the market." The settlement does secure an important change in the competitive situation; it removes from consideration the most motivated challenger, and the one closest to introducing competition. Similarly, although it may be correct in a literal sense that a settlement "clear[s] the field," the implication is very different from that drawn by the Second Circuit [in *Tamoxifen*]: the most vigorous challenger has been removed from the field, thereby removing an important source of early competition.

Hemphill, 81 N.Y.U. L. Rev. at 1586 (footnotes omitted).

Thus, buying off the first ANDA-IV filer could protect the monopoly from any threat of competition for years even if it is premised on a "fatally weak" patent. In the years that may be necessary for subsequent generic challengers to take their position on the "cleared field," holders of weak or defective patents will continue to extract unjustified billions from consumers before the "money runs out" or "reverse payments"

cease. *See* Hovenkamp, § 7.4 at 7-37.[16] The point is analogous to John Maynard Keynes's retort to free market theorists, who argued that an uncontrolled market will correct imbalances "in the long run." "*Long run* is a misleading guide to current affairs. *In the long run* we are all dead." *Bartlett's Familiar Quotations* (16th ed. 1992), p. 652 (emphasis in original; quoting *A Tract on Monetary Reform* [1923], ch. 3).

In addition, as recognized by commentators, the Second Circuit did not appreciate the anticompetitive implications, especially with respect to the legally erroneous suggestion that a generic manufacturer *other* than the first ANDA-IV filer to challenge the innovator's patent could be eligible for the 180 day Exclusivity Period. *See* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 2046 p. 491 (Supp. 2006).

> [T]he panel majority relied upon the erroneous view that bounty [*i.e.*, 180 day Exclusivity Period] eligibility *does* cede to other [subsequent] filers. According to the majority, the innovator's settlement with the first filer, by neutralizing the competitive threat of the first filer, "opened the [relevant] patent to immediate challenge by other potential generic manufacturers, which did indeed follow – spurred by the additional incentive (at the time) of potentially securing the 180 day exclusivity period available upon a victory in a subsequent infringement action." The majority apparently believed that, at least during the period of the FDA's successful defense interpretation (that is what the panel means by "at the time"), exclusivity eligibility ceded to a later filer.

Hemphill, 81 N.Y.U. L. Rev. at 1584-85 (footnote omitted; emphasis in original). The Second Circuit clearly did not have

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16. As the dissent recognized, "[a]nother generic manufacturer will have to wait at least thirty months after the litigation is commenced against it to begin production." Pet. App. 123a.

"a correct understanding of the exclusivity period [, which] is necessary to a proper understanding of generic firm incentives." *Id.* at 1585.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT FILED AUGUST 10, 2006

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

August Term, 2003

(Argued: July 12, 2004. Decided: November 2, 2005

As amended: August 10, 2006)

Docket No. 03-7641

In Re: Tamoxifen Citrate Antitrust Litigation

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L.-A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH & HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Plaintiffs-Appellants,

Appendix A

- v -

BARR LABS. INC., ASTRAZENECA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Defendants-Appellees.

Before: POOLER, SACK, and RAGGI, *Circuit Judges.* Pooler, Circuit Judge, dissents in a separate opinion.

SACK, *Circuit Judge.*

This appeal, arising out of circumstances surrounding a lawsuit in which a drug manufacturer alleged that its patent for the drug tamoxifen citrate ("tamoxifen") was about to be infringed, and the suit's subsequent settlement, requires us to address issues at the intersection of intellectual property law and antitrust law. Although the particular factual circumstances of this case are unlikely to recur, the issues presented have been much litigated and appear to retain their vitality.

The plaintiffs appeal from a judgment of the United States District Court for the Eastern District of New York (I. Leo Glasser, *Judge*) dismissing their complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). The plaintiffs claim that the defendants conspired, under an agreement settling a patent infringement lawsuit among the defendants in 1993 while an appeal in that lawsuit was pending, to monopolize the market for tamoxifen-the most widely prescribed drug for the treatment of breast cancer-by suppressing competition from generic versions of the drug.

Appendix A

The settlement agreement included, among other things, a so-called "reverse payment" of $21 million from the defendant patent-holders Zeneca, Inc., AstraZeneca Pharmaceuticals LP, and AstraZeneca PLC (collectively "Zeneca") to the defendant generic manufacturer Barr Laboratories, Inc. ("Barr"), and a license from Zeneca to Barr allowing Barr to sell an unbranded version of Zeneca-manufactured tamoxifen. The settlement agreement was contingent on obtaining a *vacatur* of the judgment of the district court that had heard the infringement action holding the patent to be invalid.

The district court in the instant case concluded that the settlement did not restrain trade in violation of the antitrust laws, and that the plaintiffs suffered no antitrust injury from that settlement. Because we conclude that we have jurisdiction to hear the appeal and that the behavior of the defendants alleged in the complaint would not violate antitrust law, we affirm the judgment of the district court.

REGULATORY BACKGROUND

Before setting forth the salient facts of this case and addressing the merits of the plaintiffs' appeal, it may be helpful to outline the relevant regulatory background.[1]

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1. A similar description of the relevant statutes and regulations is set forth in the Eleventh Circuit's opinion in *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1296-98 (11th Cir.2003), *cert. denied*, 125 S.Ct. 308 (2004), and the District of Columbia Circuit's opinion in *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 801-02 (D.C.Cir.2001), *cert. denied*, 535 U.S. 931, 122 S.Ct. 1305, 152 L.Ed.2d 216 (2002).

Appendix A

The Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified at scattered sections of title 21 of the United States Code), prohibits the introduction or delivery for introduction into interstate commerce of "any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of [21 U.S.C. § 355] is effective with respect to such drug." 21 U.S.C. § 355(a). Subsection (b) describes the process of filing a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA"), which is typically a costly and time-consuming procedure in which the applicant attempts to establish the safety and effectiveness of the drug. *Id.* § 355(b). In 1984, in order to accelerate the approval process for low-cost generic versions of established drugs, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub.L. No. 98-417, 98 Stat. 1585 (codified at scattered sections of titles 21 and 35 of the United States Code). Among other things, the Act added subsection (j) to section 355. Hatch-Waxman Act § 101. Subsection (j) provides for an Abbreviated New Drug Application ("ANDA") to the FDA for the bioequivalent form of a drug already approved for safety and effectiveness. 21 U.S.C. § 355(j)(1), (j)(2)(A), (j)(7)(A). Subsection (j)(7)(A) further provides that the Secretary of the FDA will create and maintain a list of such approved drugs. *Id.* § 355(j)(7)(A). This list, *Approved Drug Products with Therapeutic Equivalence Evaluations*, is commonly known as the "Orange Book."[2] *See id.;* http://www.fda.gov/cder/orange/default.htm.

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2. The ANDA process was intended to be available to manufacturers of generic versions of approved drugs. "A generic (Cont'd)

Appendix A

An ANDA filer must certify, with respect to each patent that claims the listed drug for the bioequivalent of which the ANDA filer is seeking approval,[3] either that no patent was filed for the listed drug (a "paragraph I" certification), that the patent has expired (a "paragraph II" certification), that the patent will expire on a specified date and the ANDA filer will not market the drug until that date (a "paragraph III" certification), or that the patent is invalid or would not be infringed by the manufacture, use, or sale of the new drug (a "paragraph IV" certification). 21 U.S.C. § 355(j)(2)(A)(vii).

(Cont'd)
version . . . contains the same active ingredients, but not necessarily the same inactive ingredients, as the pioneer drug. A generic drug, as the name implies, is ordinarily sold without a brand name and at a lower price." *Andrx Pharms.*, 256 F.3d at 801 n. 1. Filing an ANDA allows a generic drug manufacturer to avoid the costly and time-consuming process of demonstrating safety and efficacy, allowing the manufacturer to rely on the FDA's earlier findings concerning the brand-name drug's NDA, and thereby facilitates quicker market entry by generic manufacturers. *See id.* at 801.

3. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(b)(1).

Appendix A

An ANDA filer that elects a paragraph IV certification must notify each affected patent owner of the certification. *Id.* § 355(j)(2)(B)(i). The patent owner then has forty-five days after the date it receives such notice to bring suit against the ANDA filer for patent infringement. *Id.* § 355(j)(5)(B)(iii). If no patent owner brings such a lawsuit during this period, the FDA may immediately approve the ANDA. *Id.* If, however, the patent owner brings suit during this period, the FDA's final approval of the ANDA is stayed for thirty months after the date the patent owner received the requisite notice or until a district court[4] returns a decision as to the validity of the patent or its infringement if it does so before the thirty-month period expires. *Id.*

Any approval letter sent by the FDA before the expiration of the prescribed stay and before a court ruling of patent invalidity or non-infringement is tentative. *See* 21 C.F.R. § 314.105(d). If before the thirty months expire a court rules that the patent is either invalid or not infringed, the tentative approval of the ANDA is made effective as of the

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4. At the time of the settlement in this case, the statute did not specify that a district court decision would end the 30-month stay, and the FDA interpreted the statute to require a court decision "from which no appeal can be or has been taken." Ctr. for Drug Evaluation & Research (CDER), Food & Drug Admin., U.S. Dep't of Health & Human Servs., *Guidance for Industry: Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act* 2 (Mar.2000) (quoting 21 C.F.R. § 314.107(e)(1) (1999)) (hereinafter CDER, *Court Decisions*), *available at* http:// www.fda.gov/cder/guidance/3659fnl.pdf (last visited May 12, 2005). In 2000, the FDA changed its interpretation to include any district court decision. *See id.* at 3-5.

date of judgment. 21 U.S.C. § 355(j)(5)(B)(iii)(I). If after thirty months there has been no ruling on patent validity or infringement and the stay expires, the ANDA filer can distribute and market the drug but, depending on the court's later patent ruling, an ANDA filer that chooses to follow this course may thereafter become liable for infringement damages if infringement is found. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F.Supp.2d 740, 744 (E.D.N.Y.2001) ("*Cipro I*").

As an incentive for generic manufacturers to choose the paragraph IV certification route and, in the course of pursuing such applications, to challenge weak patents, the Hatch-Waxman Act offers the first ANDA filer with a paragraph IV certification, under certain conditions, the opportunity to market its generic drug exclusively for 180 days. To this end, the FDA may not approve the ANDA of a subsequent filer until 180 days after the earlier of the date (1) the first ANDA filer commercially markets the generic drug or (2) a court of competent jurisdiction concludes that the patent in question is invalid or not infringed.[5] 21 U.S.C. § 355(j)(5)(B)(iv)(I)-(II).

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5. Like its interpretation of the type of court decision sufficient to end the 30-month stay of final FDA approval described above, at the time of the settlement in this case and until 2000, the FDA interpreted a court decision required to trigger the 180-day period to mean only a court decision "from which no appeal can be or has been taken." *See* CDER, *Court Decisions*, *supra*, at 2 (quoting 21 C.F.R. § 314.107(e)(1) (1999)). That interpretation was subsequently changed in 2000, when the FDA concluded that a patent invalidity decision by a district court would be sufficient to trigger the commencement of the 180-day period. *See id.* at 3-5.

Appendix A

Until 1998 (and, therefore, at the time of the settlement that is the subject of this appeal), the 180-day exclusivity period was available to the first ANDA filer to elect a paragraph IV certification, but only if the ANDA filer successfully defended against a lawsuit for infringement of the relevant patent. *See* 21 C.F.R. § 314.107(c)(1) (1995). This so-called "successful defense" requirement was challenged in 1997 in two separate lawsuits. In each, the circuit court rejected the requirement as inconsistent with the Hatch-Waxman Act. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C.Cir.1998); *Granutec, Inc. v. Shalala*, 139 F.3d 889, 1998 WL 153410, at *7 (4th Cir. Apr.3, 1998), 1998 U.S.App. LEXIS 6685, at *19-*21 (unpublished opinion).

In June 1998, in response to these decisions, the FDA published a "Guidance for Industry." *See* Ctr. for Drug Evaluation & Research, Food & Drug Admin., U.S. Dep't of Health and Human Servs., *Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act* (June 1998), *available at* http:// www.fda.gov/cder/guidance/2576fnl.pdf (last visited May 12, 2005). In the "Guidance," the FDA expressed its intention to remove the "successful defense" requirement formally through rulemaking and made clear that thereafter even ANDA paragraph IV filers that are not the subject of lawsuits will be eligible for the 180-day exclusivity period. *Id.* at 4-5. "Until such time as the rulemaking process [was] complete, FDA . . . regulate[d] directly from the statute, and . . . ma[de] decisions on 180-day generic drug exclusivity on a case-by-case basis." *Id.* at 4. Later that year, the FDA formally revoked the

"successful defense" requirement. *See* Effective Date of Approval of an Abbreviated New Drug Application, 63 Fed.Reg. 59,710, 59,710 (Nov. 5, 1998), 21 C.F.R. § 314.107 (1999).

FACTUAL AND PROCEDURAL BACKGROUND

Tamoxifen, the patent for which was obtained by Imperial Chemical Industries, PLC, ("ICI") on August 20, 1985, is sold by Zeneca (a former subsidiary of ICI which succeeded to the ownership rights of the tamoxifen patent) under the trade name Nolvadex®.[6] Tamoxifen is the most widely prescribed drug for the treatment of breast cancer. Indeed, it is the most prescribed cancer drug in the world. In December 1985, four months after ICI was awarded the patent, Barr filed an ANDA with the FDA requesting the agency's approval for Barr to market a generic version of tamoxifen that it had developed. Barr amended its ANDA in September 1987 to include a paragraph IV certification.

In response, on November 2, 1987-within the required forty-five days of Barr's amendment of its ANDA to include a paragraph IV certification-ICI filed a patent infringement lawsuit against Barr and Barr's raw material supplier, Heumann Pharma GmbH & Co. ("Heumann"), in the United States District Court for the Southern District of New York.[7]

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6. In 2001, Zeneca's domestic sales of tamoxifen amounted to $442 million.

7. Soon thereafter, Heumann was dismissed as a defendant after it agreed to be bound by a determination in that case as to the validity of the tamoxifen patent. Compl. ¶ 40.

See Imperial Chem. Indus., PLC v. Barr Labs., Inc., 126 F.R.D. 467, 469 (S.D.N.Y.1989). On April 20, 1992, the district court (Vincent L. Broderick, *Judge*) declared ICI's tamoxifen patent invalid based on the court's conclusion that ICI had deliberately withheld "crucial information" from the Patent and Trademark Office regarding tests that it had conducted on laboratory animals with respect to the safety and effectiveness of the drug. *See Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F.Supp. 619, 626-27 (S.D.N.Y.1992) (" *Tamoxifen I* "). Those tests had revealed hormonal effects "opposite to those sought in humans," which, the court found, could have "unpredictable and at times disastrous consequences." *Id.* at 622.

ICI appealed the district court's judgment to the United States Court of Appeals for the Federal Circuit. In 1993, while the appeal was pending, the parties entered into a confidential settlement agreement (the "Settlement Agreement") which is the principal subject of this appeal. In the Settlement Agreement, Zeneca (which had succeeded to the ownership rights of the patent) and Barr agreed that in return for $21 million and a non-exclusive license to sell Zeneca-manufactured tamoxifen in the United States under Barr's label, rather than Zeneca's trademark Nolvadex®, Barr would change its ANDA paragraph IV certification to a paragraph III certification, thereby agreeing that it would not market its own generic version of tamoxifen until Zeneca's patent expired in 2002. *See In re Tamoxifen Citrate Antitrust Litig.*, 277 F.Supp.2d 121, 125-26 (E.D.N.Y.2003) (*"Tamoxifen II"*). Zeneca also agreed to pay Heumann $9.5 million immediately, and an additional $35.9 million over the following ten years. The parties further agreed that if the

tamoxifen patent were to be subsequently declared invalid or unenforceable in a final and (in contrast to the district court judgment in *Tamoxifen I*) unappealable judgment by a court of competent jurisdiction, Barr would be allowed to revert to a paragraph IV ANDA certification. Thus if, in another lawsuit, a generic marketer prevailed as Barr had prevailed in *Tamoxifen I*, and that judgment was either not appealed or was affirmed on appeal, Barr would have been allowed to place itself in the same position (but for the 180-day head start, if it was available) that it would have been in had it prevailed on appeal in *Tamoxifen I*, rather than settling while its appeal was pending in the Federal Circuit.

The plaintiffs allege that as a part of the Settlement Agreement, Barr "understood" that if another generic manufacturer attempted to market a version of tamoxifen, Barr would seek to prevent the manufacturer from doing so by attempting to invoke the 180-day exclusivity right possessed by the first "paragraph IV" filer. Compl. ¶ 58. According to the plaintiffs, this understanding among the defendants effectively forestalled the introduction of any generic version of tamoxifen, because, five years later-only a few weeks before other generic manufacturers were to be able to begin marketing their own versions of tamoxifen-Barr did in fact successfully claim entitlement to the exclusivity period. It thereby prevented those manufacturers from entering the tamoxifen market until 180 days after Barr triggered the period by commercially marketing its own generic version of the drug. In fact, Barr had not yet begun marketing its own generic version and had little incentive to do so because, pursuant to the Settlement Agreement, it was already able to market Zeneca's version of tamoxifen.

Meanwhile, pursuant to the Settlement Agreement which was contingent on the *vacatur* of the district court judgment in *Tamoxifen I*, Barr and Zeneca filed a "Joint Motion to Dismiss the Appeal as Moot and to Vacate the Judgment Below." *See Tamoxifen II*, 277 F.Supp.2d at 125. The Federal Circuit granted the motion, thereby vacating the district court's judgment that the patent was invalid. *See Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811, 1993 WL 118931, at *1, U.S. App. LEXIS 14872, at *1-*2 (Fed.Cir. Mar. 19, 1993) (unpublished opinion). Such a *vacatur*, while generally considered valid as a matter of appellate procedure by courts at the time of the Settlement Agreement, *see U.S. Philips Corp. v. Windmere Corp.*, 971 F.2d 728, 731 (Fed.Cir.1992), was shortly thereafter held to be invalid in nearly all circumstances by the Supreme Court, *see U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship*, 513 U.S. 18, 27-29, 115 S.Ct. 386, 130 L.Ed.2d 233 (1994).[8]

In the years after the parties entered into the Settlement Agreement and the Federal Circuit vacated the district court's judgment,[9] three other generic manufacturers filed ANDAs

8. The rule in *U.S. Bancorp* does not apply retroactively. *See U.S. Philips Corp. v. Sears Roebuck & Co.*, 55 F.3d 592, 598 (Fed.Cir.), *cert. denied*, 516 U.S. 1010, 116 S.Ct. 567, 133 L.Ed.2d 492 (1995).

9. After the Settlement Agreement was entered into and the *vacatur* ordered, Barr began to market its licensed version of Zeneca's tamoxifen, selling its product to distributors and wholesalers at a 15 percent discount to the brand-name price, which translated into a price to consumers about five percent below Zeneca's otherwise identical Nolvadex® brand-name version. Barr soon captured about 80 percent of the tamoxifen market.

with paragraph IV certifications to secure approval of their respective generic versions of tamoxifen: Novopharm Ltd., in June 1994, Mylan Pharmaceuticals, Inc., in January 1996, and Pharmachemie, B.V., in February 1996.[10] *See Tamoxifen II*, 277 F.Supp.2d at 126-27. Zeneca responded to each of these certifications in the same manner that it had responded to Barr's: by filing a patent infringement lawsuit within the forty-five day time limit provided by 21 U.S.C. § 355(j)(5)(B)(iii). *See id.* In each case, the court rejected the generic manufacturer's attempt to rely on the vacated *Tamoxifen I* decision, and-contrary to the *Tamoxifen I* judgment-upheld the validity of Zeneca's tamoxifen patent. *See Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144, 1997 WL 168318, at *2-*4 (Fed.Cir. Apr.10, 1997), 1997 U.S.App. LEXIS 6634, at *4-*11 (unpublished opinion) (affirming the judgment of the United States District Court for the District of Maryland declining to give *Tamoxifen I* collateral estoppel effect or to apply *U.S. Bancorp* retroactively and deciding that Zeneca's patent was valid); *Zeneca Ltd. v. Pharmachemie B.V.*, 2000 WL 34335805, at *15, 2000 U.S. Dist LEXIS 22631, at *51-*53 (D.Mass. Sept.11, 2000) (concluding that Zeneca had not engaged in inequitable conduct and that the patent was valid); *AstraZeneca UK Ltd. v. Mylan Pharms., Inc.*, No. 00-2239, slip op. at 2-3 (W.D.Pa. Nov. 30, 2000) (entering stipulated consent order that FDA approval for Mylan would not be effective before the expiration of the tamoxifen patent).

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10. Pharmachemie initially filed a paragraph III certification in August 1994, but later amended it to include a paragraph IV certification. *See Tamoxifen II*, 277 F.Supp.2d at 126.

Appendix A

While Mylan and Pharmachemie's lawsuits were pending in district court, the FDA's "successful defense" rule, requiring that a generic manufacturer seeking to market an allegedly patented drug "successfully defend" its patent infringement lawsuit in order to receive the 180-day exclusivity period-which at the time the Settlement Agreement was entered into would have excluded Barr from benefitting from the exclusivity period-was, as noted, held invalid. *See Mova Pharm. Corp. v. Shalala*, 955 F.Supp. 128, 130-32 (D.D.C.1997), *aff'd in part and rev'd in part on other grounds*, 140 F.3d 1060 (D.C.Cir.1998); *Granutec, Inc. v. Shalala*, 139 F.3d 889, 1998 WL 153410, at *7 (4th Cir. Apr.3, 1998), 1998 U.S.App. LEXIS 6685, at *19-*21 (unpublished opinion). In June 1998, at the time the FDA removed the requirement, Barr-armed with the new rule rendering the first ANDA paragraph IV filer eligible for the 180-day exclusivity period even if it had not successfully defended a patent infringement suit-attempted to block final FDA approval of other generic versions of tamoxifen by claiming entitlement to the 180-day exclusivity period. *See Tamoxifen II*, 277 F.Supp.2d at 127 (citing "Petition for Stay of Action" filed with the FDA on June 26, 1998).

At the time, Pharmachemie had received tentative approval from the FDA to distribute its version of the drug, Mylan was awaiting approval to do the same, and both Pharmachemie and Mylan's thirty-month stays under section 355(j)(5)(B)(iii), triggered by Zeneca's infringement lawsuits, were soon to expire. *See* Compl. ¶¶ 61-63 (noting that the 30-month stay for Mylan was scheduled to expire on July 10, 1998, and for Pharmachemie in August 1998); *Pharmachemie B.V. v. Barr Labs., Inc.*, 276 F.3d 627, 630

(D.C.Cir.2002) (noting that Pharmachemie was granted tentative approval on April 3, 1997); *Mylan Pharms. Inc. v. Henney*, 94 F.Supp.2d 36, 44 (D.D.C.2000), *vacated and dismissed as moot sub nom. Pharmachemie B.V. v. Barr Labs., Inc.*, 284 F.3d 125 (D.C.Cir.2002) (per curiam). Because of the rule change, however, the FDA was able to, and on March 2, 1999, did, grant Barr's petition to confirm its entitlement to the exclusivity period despite the fact that it had settled, rather than "successfully defended" against, Zeneca's lawsuit. *See Tamoxifen II*, 277 F.Supp.2d at 127. The FDA's action effectively delayed the marketing of other generic versions of tamoxifen unless and until Barr triggered and exhausted its 180-day exclusivity period by selling its own generic form of the drug, rather than the version manufactured by Zeneca. As noted, Barr had little incentive to do so because it was already distributing Zeneca's version of tamoxifen.

Pharmachemie and Mylan challenged the FDA's decision. On March 31, 2000, in *Mylan Pharmaceuticals*, the United States District Court for the District of Columbia ruled in Pharmachemie's and Mylan's favor. 94 F.Supp.2d at 54. It concluded that, although Judge Broderick's ruling of invalidity in *Tamoxifen I* had been vacated by the Settlement Agreement, that ruling was still a court decision sufficient to trigger Barr's 180-day exclusivity period, which therefore had already expired. *See Mylan Pharms.*, 94 F.Supp.2d at 54. As a result, on June 26, 2000, the FDA revoked Barr's claim to the 180-day exclusivity period. *See Tamoxifen II*, 277 F.Supp.2d at 127.

On appeal, however, the District of Columbia Circuit vacated the district court's decision as moot. *Pharmachemie*, 276 F.3d at 634; *Pharmachemie*, 284 F.3d at 125. The court noted that subsequent to the FDA's decision to approve Barr's application, the district court had ruled against Pharmachemie in Zeneca's patent infringement lawsuit against it. *See Pharmachemie*, 276 F.3d at 629. Thus, even if, as the district court held in *Mylan*, Barr's 180-day exclusivity period had run, Pharmachemie and Mylan[11] were prohibited by the judgments against them in the patent litigation from marketing their generic versions of tamoxifen until Zeneca's patent expired. Zeneca's patent on tamoxifen expired on August 20, 2002, and generic manufacturers began marketing their own versions of tamoxifen soon thereafter.

Proceedings in the District Court

While these generic manufacturers were litigating the validity of Zeneca's patent on tamoxifen, consumers and consumer groups in various parts of the United States filed some thirty lawsuits challenging the legality of the 1993 Settlement Agreement between Zeneca and Barr. *See Tamoxifen II*, 277 F.Supp.2d at 127. Those lawsuits were subsequently transferred by the Judicial Panel on Multidistrict Litigation to the United States District Court for the Eastern District of New York. Subsequently, a consolidated class action complaint embodying the claims was filed. *In re Tamoxifen Citrate Antitrust Litig.*, 196 F.Supp.2d 1371 (2001); *Tamoxifen II*, 277 F.Supp.2d at 127.

11. Mylan had agreed to follow the *Pharmachemie* court decision. *See Tamoxifen II*, 277 F.Supp.2d at 127; *AstraZemeca UK Ltd.*, No. 00-2239, slip op. at 2-3.

Appendix A

In the consolidated lawsuit, the plaintiffs alleged that the Settlement Agreement unlawfully (1) enabled Zeneca and Barr to resuscitate a patent that the district court had already held to be invalid and unenforceable; (2) facilitated Zeneca's continuing monopolization of the market for tamoxifen; (3) provided for the sharing of unlawful monopoly profits between Zeneca and Barr; (4) maintained an artificially high price for tamoxifen; and (5) prevented competition from other generic manufacturers of tamoxifen. *See Tamoxifen II*, 277 F.Supp.2d at 127-28. At the heart of the lawsuit was the contention that the Settlement Agreement enabled Zeneca and Barr effectively to circumvent the district court's invalidation of Zeneca's tamoxifen patent in *Tamoxifen I*, which, the plaintiffs asserted, would have been affirmed by the Federal Circuit. The result of such an affirmance, according to the plaintiffs, would have been that Barr would have received approval to market a generic version of tamoxifen; Barr would have begun marketing tamoxifen, thereby triggering the 180-day exclusivity period; other generic manufacturers would have introduced their own versions of tamoxifen upon the expiration of the exclusivity period, with Zeneca collaterally estopped from invoking its invalidated patent as a defense; and, as a result, the price for tamoxifen would have declined substantially below the levels at which the Zeneca-manufactured drug in fact sold in the market shared by Zeneca and Barr through the Settlement Agreement. *Id.* at 128. The defendants moved to dismiss the class action complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted.

Appendix A

On May 15, 2003, in a thorough and thoughtful opinion, the district court granted the defendants' motion to dismiss. *See id.* at 140. The court noted that although market-division agreements between a monopolist and a potential competitor ordinarily violate the Sherman Act, they are not necessarily unlawful when the monopolist is a patent holder. *Id.* at 128-29. Pursuant to a patent grant, the court reasoned, a patent holder may settle patent litigation by entering into a licensing agreement with the alleged infringer without running afoul of the Sherman Act. *Id.* at 129. Yet, the court continued, a patent holder is prohibited from acting in bad faith "beyond the limits of the patent monopoly" to restrain or monopolize trade. *Id.* (quoting *United States v. Line Material Co.*, 333 U.S. 287, 308, 68 S.Ct. 550, 92 L.Ed. 701 (1948) (internal quotation marks omitted)).

Analyzing the terms and impact of the Settlement Agreement, the district court concluded that the agreement permissibly terminated the litigation between the defendants, which "cleared the field for other generic manufacturers to challenge the patent." *Id.* at 133. "Instead of leaving in place an additional barrier to subsequent ANDA filers, the Settlement Agreement in fact removed one possible barrier to final FDA approval-namely, the existence of ongoing litigation between an existing ANDA filer and a subsequent filer." *Id.* To the court, this factor distinguished the case from similar cases in which other circuits had held settlement agreements to be unlawful, where the agreement in question did not conclude the underlying litigation and instead prolonged the period during which other generic manufacturers could not enter the market. *Id.* (distinguishing the Settlement Agreement from the agreements addressed in

In re Terazosin Hydrochloride Antitrust Litig., 164 F.Supp.2d 1340, 1346-47 (S.D.Fla.2000), *rev'd sub nom. Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir.2003), *cert. denied*, 125 S.Ct. 308 (2004), and *In re Cardizem CD Antitrust Litig.*, 105 F.Supp.2d 618, 632 (E.D.Mich.2000), *aff'd*, 332 F.3d 896 (6th Cir.2003), *cert. denied sub nom. Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S. 939, 125 S.Ct. 307, 160 L.Ed.2d 248 (2004)).

The district court was also of the view that the defendants could not be held liable for Barr's FDA petition to preserve its 180-day exclusivity period even if this was a term of the defendants' negotiated Settlement Agreement. *Id.* at 135. It reasoned that at the time of settlement, Barr could not have successfully pursued its FDA application because the FDA continued to apply the "successful defense" rule until 1997. *Id.* at 134. It was only after 1997 that Barr petitioned the FDA to preserve its exclusivity period. The court concluded that Barr's petition was

> an attempt to petition a governmental body in order to protect an arguable interest in a statutory right based on recent developments in the court and at the FDA. As such, the FDA Petition was protected activity under the First Amendment, and long-settled law established that the Sherman Act, with limited exceptions, does not apply to petitioning administrative agencies.

Id. at 135. The court concluded that the plaintiffs' complaint therefore did not sufficiently allege a bad-faith settlement in violation of the Sherman Act. *Id.* at 136.

The district court also concluded that even if the plaintiffs had stated an antitrust violation, they did not suffer antitrust injury from either Barr's exclusivity period or the Settlement Agreement and the resulting *vacatur* of the district court's judgment in *Tamoxifen I* invalidating the tamoxifen patent. *Id.* at 136-38. The court noted that "[a]ntitrust injury ··· must be caused by something other than the regulatory action limiting entry to the market." *Id.* at 137. The court attributed "the lack of competition in the market" not to "the deployment of Barr's exclusivity period, but rather [to] the inability of the generic companies to invalidate or design around" the tamoxifen patent, and their consequent loss of the patent litigation against Zeneca. *Id.* This was so, the district court concluded, even if Barr's petition to the FDA had delayed the approval of Mylan's ANDA. *Id.* at 137. Any "injury" suffered by the plaintiffs, said the court, "is thus not antitrust injury, but rather the result of the legal monopoly that a patent holder possesses." *Id.* at 138.

The district court also rejected the plaintiffs' contention that "the settlement and *vacatur* deprived other generic manufacturers of the ability to make the legal argument that the [*Tamoxifen I*] judgment (if affirmed) would collaterally estop Zeneca from claiming the [tamoxifen] patent was valid in future patent litigation with other ANDA filers." *Id.* It reasoned that there is no basis for the assertion that "forcing other generic manufacturers to litigate the validity of the [tamoxifen] patent[ ] is an injury to competition." *Id.* The court also referred to the other generic manufacturers' subsequent litigation against Zeneca over the validity of the tamoxifen patent, in which Zeneca prevailed, as additional reason to reject the plaintiffs' assertion that the Federal

Circuit would have affirmed Judge Broderick's judgment invalidating the tamoxifen patent. *Id.*

The district court therefore dismissed the plaintiffs' Sherman Act claims. *Id.* It also dismissed the plaintiffs' state-law claims, which had alleged violations of the antitrust laws of seventeen states and violations of consumer protection and unfair competition laws of twenty-one states, because those claims were based on the same allegations as the plaintiffs' federal antitrust claims. *Id.* at 138-40. The plaintiffs appeal the dismissal of their claims.

On July 28, 2003, the defendants moved in this Court to transfer the appeal to the Federal Circuit on the ground that that court alone has jurisdiction to entertain this appeal. For the reasons stated below, we deny the defendants' motion and affirm the district court's judgment dismissing the plaintiffs' complaint.

DISCUSSION

I. Jurisdiction

The defendants argue that this Court does not have jurisdiction to hear this appeal because the case arises under federal patent law and the Federal Circuit has exclusive appellate jurisdiction over such appeals. The plaintiffs respond that we, rather than the Federal Circuit, have appellate jurisdiction because this case does not, on the basis of their well-pleaded complaint, substantially turn on issues of federal patent law. We agree with the plaintiffs.

Appendix A

The United States Court of Appeals for the Federal Circuit has exclusive jurisdiction over an appeal from a federal district court "if the jurisdiction of that court was based, in whole or in part, on section 1338 of [title 28]," with exceptions not pertinent here. 28 U.S.C. § 1295(a)(1). Section 1338, in turn, provides that federal district courts shall have original and exclusive jurisdiction "of any civil action arising under any Act of Congress relating to patents." *Id.* § 1338(a). Therefore, whether the Federal Circuit has jurisdiction over the instant case "turns on whether this is a case 'arising under' a federal patent statute." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807, 108 S.Ct. 2166, 100 L.Ed.2d 811 (1988).

A case "arises under" federal patent law if "a well-pleaded complaint establishes either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Id.* at 809, 108 S.Ct. 2166.[12] This is determined "from what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration, unaided by anything alleged in anticipation or

12. The *Christianson* Court employed the "well-pleaded complaint" test that is routinely applied to determine whether a federal district court has federal-question jurisdiction. *See Christianson*, 486 U.S. at 808, 108 S.Ct. 2166 (quoting *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 27-28, 103 S.Ct. 2841, 77 L.Ed.2d 420 (1983)); *see also, e.g., Aetna Health Inc. v. Davila*, 542 U.S. 200, 124 S.Ct. 2488, 2494, 159 L.Ed.2d 312 (2004); *Empire HealthChoice Assurance, Inc. v. McVeigh*, 396 F.3d 136, 140 (2d Cir.2005); *Bracey v. Bd. of Educ.*, 368 F.3d 108, 113 (2d Cir.2004).

avoidance of defenses which it is thought the defendant may interpose." *Id.* (internal quotation marks and citation omitted). "[A] case raising a federal patent-law defense does not, for that reason alone, arise under patent law, even if the defense is anticipated in the plaintiff's complaint, and even if both parties admit that the defense is the only question truly at issue in the case." *Id.* (internal quotation marks and citation omitted).

Moreover, even if one theory supporting a claim essentially turns on an issue arising under patent law, as long as there is at least one alternative theory supporting the claim that does not rely on patent law, there is no "arising under" jurisdiction under 28 U.S.C. § 1338. In that case, as the Supreme Court concluded in *Christianson:* "Since there are reasons completely unrelated to the provisions and purposes of federal patent law why petitioners may or may not be entitled to the relief they seek under their monopolization claim, the claim does not arise under federal patent law." *Id.* at 812, 108 S.Ct. 2166 (internal quotation marks, citation, and alterations omitted); *see also id.* at 810, 108 S.Ct. 2166 ("[A] claim supported by alternative theories in the complaint may not form the basis for § 1338(a) jurisdiction unless patent law is essential to each of those theories.").

Applying these principles to the case at hand, we conclude that we have jurisdiction to entertain this appeal. As we explain below, the defendants' contention that "all of [p]laintiffs' claims arise under the patent law because each requires [p]laintiffs to establish that the [tamoxifen] patent was invalid or unenforceable," Appellees' Reply Mem. Supp. Mot. to Transfer Appeal at 2, is mistaken. The theories that

would enable the plaintiffs to prevail do not require us to examine whether Judge Broderick's invalidation of the tamoxifen patent would have been upheld on appeal or whether the tamoxifen patent was otherwise enforceable and infringed.

If the plaintiffs alleged facts that, if proved, would establish that the Settlement Agreement provided the defendants with benefits exceeding the scope of the tamoxifen patent, they would succeed in alleging an antitrust violation. And if the plaintiffs plausibly alleged that the defendants entered into an agreement to manipulate the 180-day exclusivity period to the defendants' joint benefit, and if they were able to prove based on the facts alleged that they suffered antitrust injury as a result of that agreement, then that, too, would likely be sufficient to state an antitrust violation. Were they to allege and then prove facts sufficient to support either of these theories, the argument that the Settlement Agreement was unlawful "[e]ven if the [tamoxifen p]atent is presumed valid and enforceable," Compl. ¶ 55, would, in our view, be persuasive.

Because we conclude that there are "reasons completely unrelated to the provisions and purposes of the patent laws why the plaintiff[s] may or may not be entitled to the relief [they] seek[ ]," *Christianson*, 486 U.S. at 810, 108 S.Ct. 2166 (internal quotation marks, citation, and alterations omitted), we have jurisdiction to entertain this appeal.

Appendix A

II. Standard of Review

We review a decision on a motion to dismiss *de novo*. *Gregory v. Daly*, 243 F.3d 687, 691 (2d Cir.2001).

"A pleading which sets forth a claim for relief . . . shall contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." Fed.R.Civ.P. 8(a)(2). "Given the Federal Rules' simplified standard for pleading, a court may dismiss a complaint only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 514, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002) (internal quotation marks, citation, and alteration omitted). There is no heightened pleading requirement in antitrust cases. *See Twombly v. Bell Atl. Corp.*, 425 F.3d 99, 108-13 (2d Cir.2005).

In reviewing a decision on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), we "must accept as true all the factual allegations in the complaint," *Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164, 113 S.Ct. 1160, 122 L.Ed.2d 517 (1993), and "draw all reasonable inferences in plaintiffs' favor," *Freedom Holdings Inc. v. Spitzer*, 357 F.3d 205, 216 (2d Cir.2004). To survive a motion to dismiss, a plaintiff bringing suit under section 1 of the Sherman Act need not allege facts that exclude the possibility that the behavior of which complaint is made is legal. *See Twombly*, 425 F.3d at 111 ("[S]hort of the extremes of 'bare bones' and 'implausibility,' a complaint in an antitrust case need only contain the 'short and plain statement of the claim

showing that the pleader is entitled to relief' that Rule 8(a) requires." (citation omitted)). However, "bald assertions and conclusions of law are not adequate [to state a claim] and a complaint consisting only of naked assertions, and setting forth no facts upon which a court could find a violation of the [law], fails to state a claim under Rule 12(b)(6)." *Gregory*, 243 F.3d at 692 (internal quotation marks and citations omitted). And "[i]t is . . . improper to assume that the plaintiff can prove facts that it has not alleged or that the defendants have violated the antitrust laws in ways that have not been alleged." *Todd v. Exxon Corp.*, 275 F.3d 191, 198 (2d Cir.2001) (internal quotation marks, citation, and alterations omitted). At the same time, in antitrust cases, "plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699, 82 S.Ct. 1404, 8 L.Ed.2d 777 (1962).

III. The Plaintiffs' Antitrust Claims

A. The Tension between Antitrust Law and Patent Law

With the ultimate goal of stimulating competition and innovation, the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States,"[13]

13. "Although the Sherman Act, by its terms, prohibits every agreement 'in restraint of trade,' th[e Supreme] Court has long recognized that Congress intended to outlaw only unreasonable restraints." *State Oil Co. v. Khan*, 522 U.S. 3, 10, 118 S.Ct. 275, 139

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15 U.S.C. § 1, and "monopoliz[ation], or attempt[s] to monopolize, or combin[ations] or conspir[acies] . . . to monopolize any part of the trade or commerce among the several States," *id.* § 2.[14] By contrast, also with the ultimate

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L.Ed.2d 199 (1997). Conduct may be deemed an unreasonable restraint of trade in two ways. Conduct may be considered *per se* unreasonable because it has "such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit." *Id.*

In most cases, however, conduct will be evaluated under a "rule of reason" analysis, "according to which the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *Id.* (citation omitted).

The rule-of-reason analysis has been divided into three steps. First, a plaintiff must demonstrate "that the challenged action has had an *actual* adverse effect on competition as a whole in the relevant market." *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 543 (2d Cir.) (emphasis in original), *cert. denied*, 510 U.S. 947, 114 S.Ct. 388, 126 L.Ed.2d 337 (1993). If the plaintiff succeeds in doing so, "the burden shifts to the defendant to establish the 'pro-competitive "redeeming virtues"' of the action." *K.M.B. Warehouse Distribs., Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 127 (2d Cir.1995) (quoting *Capital Imaging Assocs.*, 996 F.2d at 543). If the defendant succeeds in meeting its burden, the plaintiff then has the burden of "show[ing] that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition." *Id.*

14. "The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the (Cont'd)

goal of stimulating competition and innovation, patent law grants an innovator "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a limited term of years. 35 U.S.C. § 154(a)(1)-(2); *see also Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215, 100 S.Ct. 2601, 65 L.Ed.2d 696 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."). It is the tension between restraints on anti-competitive behavior imposed by the Sherman Act and grants of patent monopolies under the patent laws, as complicated by the Hatch-Waxman Act, that underlies this appeal. *See, e.g., United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97, 83 S.Ct. 1773, 10 L.Ed.2d 823 (1963) ("[T]he possession of a valid patent . . . does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly.") (internal quotation marks and citation omitted); *cf. Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 802 (D.C.Cir.2001) ("Although the Congress was interested in increasing the availability of generic drugs, it also wanted to protect the patent rights of the pioneer applicants."), *cert. denied*, 535 U.S. 931, 122 S.Ct. 1305, 152 L.Ed.2d 216 (2002); *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1067 (11th Cir.2005) ("Although the exclusionary power of a patent may seem incongruous with the goals of antitrust law,

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relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71, 86 S.Ct. 1698, 16 L.Ed.2d 778 (1966).

a delicate balance must be drawn between the two regulatory schemes.").

B. The Plaintiffs' Allegations

1. Settlement of a Patent Validity Lawsuit. The plaintiffs contend that several factors-including that *Tamoxifen I* was settled after the tamoxifen patent had been held invalid by the district court, making the patent unenforceable at the time of settlement-indicate that if their allegations are proved, the defendants violated the antitrust laws. They argue that the district court in the case before us erred by treating the tamoxifen patent as valid and enforceable. Instead, they say, in accordance with the never-reviewed judgment in *Tamoxifen I*, the district court in this case should have treated the patent as presumptively invalid for purposes of assaying the sufficiency of the plaintiffs' complaint.

We begin our analysis against the backdrop of our longstanding adherence to the principle that "courts are bound to encourage" the settlement of litigation. *Gambale v. Deutsche Bank AG*, 377 F.3d 133, 143 (2d Cir.2004). "Where a case is complex and expensive, and resolution of the case will benefit the public, the public has a strong interest in settlement. The trial court must protect the public interest, as well as the interests of the parties, by encouraging the most fair and efficient resolution." *United States v. Glens Falls Newspapers, Inc.*, 160 F.3d 853, 856-57 (2d Cir.1998). As the Eleventh Circuit recently noted in drug patent litigation similar to the one before us, "There is no question that settlements provide a number of private and social

benefits as opposed to the inveterate and costly effects of litigation." *Schering-Plough*, 402 F.3d at 1075.

It is well settled that "[w]here there are legitimately conflicting [patent] claims . . . , a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act," although such a settlement may ultimately have an adverse effect on competition. *Standard Oil Co. v. United States*, 283 U.S. 163, 171, 51 S.Ct. 421, 75 L.Ed. 926 (1931); *cf. Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1369 (Fed.Cir.2001) ("[W]hile the federal patent laws favor full and free competition in the use of ideas in the public domain over the technical requirements of contract doctrine, settlement of litigation is more strongly favored by the law."); *Nestle Co. v. Chester's Mkt., Inc.*, 756 F.2d 280, 284 (2d Cir.1985) ("[T]he district court imposed the heavy burden on trademark defendants of having to continue to litigate when they would prefer to settle, a ruling without precedent."), *overruled on other grounds, U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship*, 513 U.S. 18, 27-29, 115 S.Ct. 386, 130 L.Ed.2d 233 (1994); *Duplan Corp. v. Deering Milliken, Inc.*, 540 F.2d 1215, 1220 (4th Cir.1976) ("[T]he settlement of patent litigation, in and of itself, does not violate the antitrust laws."); *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F.Supp.2d 986, 991 (N.D.Ill.2003) (Posner, J., sitting by designation) ("The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.").

Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result

would heighten the uncertainty surrounding patents and might delay innovation. *See Valley Drug*, 344 F.3d at 1308; Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L.Rev. 747, 749 (2002). Although forcing patent litigation to continue might benefit consumers in some instances, "patent settlements can . . . promote efficiencies, resolving disputes that might otherwise block or delay the market entry of valuable inventions." Joseph F. Brodley & Maureen A. O'Rourke, *Preliminary Views: Patent Settlement Agreements*, Antitrust, Summer 2002, at 53.[15] As the Fourth Circuit has observed, "It is only when settlement agreements are entered into in bad faith and are utilized as part of a scheme to restrain

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15. It is true that had the defendants not settled the underlying patent litigation and had the district court's judgment been affirmed on appeal, Zeneca would have been estopped from asserting the validity of its patent against others seeking to enter the market. *See Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 350, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971). However, it is clearly a permissible byproduct of settlement that future hypothetical plaintiffs might be forced to relitigate the same issues involved in the settled case. Furthermore, before 1994, when district court judgments were vacated as a matter of course upon settlement, *see U.S. Bancorp*, 513 U.S. at 29, 115 S.Ct. 386 (virtually ending this practice), there was similarly and permissibly no collateral estoppel effect accorded these judgments for the benefit of future hypothetical plaintiffs. *See Nestle*, 756 F.2d at 284 ("Drumbeating about the need to protect other unknown users of the trademark [in question] will ring hollow indeed in the ears of the present defendants if the peril of a reversal is realized. . . . We see no justification to force these defendants, who wish only to settle the present litigation, to act as unwilling private attorneys general and to bear the various costs and risks of litigation.").

or monopolize trade that antitrust violations may occur." *Duplan Corp.*, 540 F.2d at 1220.

We cannot judge this post-trial, pre-appeal settlement on the basis of the likelihood *vel non* of Zeneca's success had it not settled but rather pursued its appeal. As the Supreme Court noted in another context, "[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case." *Whitmore v. Arkansas*, 495 U.S. 149, 159-60, 110 S.Ct. 1717, 109 L.Ed.2d 135 (1990). Similarly, "[n]o one can be *certain* that he will prevail in a patent suit." *Asahi Glass*, 289 F.Supp.2d at 993 (emphasis in original). We cannot guess with any degree of assurance what the Federal Circuit would have done on an appeal from the district court's judgment in *Tamoxifen I*. *Cf. In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d 188, 200-01 (E.D.N.Y.2003) ("*Cipro II*") (noting that courts should not speculate about the outcome of litigation) (citing *Boehm v. Comm'r*, 146 F.2d 553 (2d Cir.), *aff'd*, 326 U.S. 287, 66 S.Ct. 120, 90 L.Ed. 78 (1945)); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F.Supp.2d 514, 529 (E.D.N.Y.2005) ("*Cipro III*") ("[M]aking the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court's assessment of the patent's validity might chill patent settlements altogether."). And because in this case any such guess is retrospective, it would in any event be of limited value in assessing the behavior of the defendants at the relevant time: when they were entering into the Settlement Agreement. *See Valley Drug*, 344 F.3d at 1306 ("[T]he reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into.") (citing, *inter alia*, *SCM Corp.*

v. Xerox Corp., 645 F.2d 1195, 1207 (2d Cir.1981), *cert. denied*, 455 U.S. 1016, 102 S.Ct. 1708, 72 L.Ed.2d 132 (1982)).

As the plaintiffs correctly point out, the Federal Circuit would have reviewed Judge Broderick's factual findings underlying his conclusion of invalidity with considerable deference, rather than engaging in a presumption of validity. *See Shelcore, Inc. v. Durham Indus., Inc.*, 745 F.2d 621, 624-25 (Fed.Cir.1984) ("The presumption of validity does not guide our analysis on appeal. Rather, we review the findings and conclusions of a district court under the appropriate standards of review."). But it takes no citation to authority to conclude that appellants prevail with some frequency in federal courts of appeals even when a high degree of deference is accorded the district courts from which the appeals are taken.[16] Accordingly, it does not follow from the deference that was due by the Federal Circuit to the district court in *Tamoxifen I* that Zeneca would have been unsuccessful on appeal. *See Cipro III*, 363 F.Supp.2d at 529 (noting that with few exceptions "courts assessing the legality of patent settlement agreements have not engaged in a *post hoc* determination of the potential validity of the underlying patent . . . when deciding whether an agreement concerning the patent violates antitrust law").

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16. It may be worth noting, although in and of itself it seems to us to prove little, that the Federal Circuit reversed district court determinations of patent invalidity at a relatively high rate during the relevant time period. *See* Donald R. Dunner *et al.*, *A Statistical Look at the Federal Circuit's Patent Decisions: 1982-1994*, 5 Fed. Cir. B.J. 151, 154-55 (1995).

The facts of this case provide an additional reason for us to embrace the general rule that we will ordinarily refrain from guessing what a court will hold or would have held. As noted earlier, federal district courts in later lawsuits seeking to enforce the tamoxifen patent concluded, contrary to the court in *Tamoxifen I*, that the patent was, in fact, valid. While we do not think that these results enable us to estimate the chances that the Federal Circuit would have reversed the judgment of the district court in *Tamoxifen I*, they at least suggest the extent to which the outcome of such proceedings may be unpredictable.[17]

The fact that the settlement here occurred after the district court ruled against Zeneca seems to us to be of little moment. There is a risk of loss in all appeals that may give rise to a desire on the part of both the appellant and the appellee to settle before the appeal is decided.[18] Settlements of legitimate

17. We thus think that it was appropriate for the district court to take these decisions into account for the limited purpose of rebutting the plaintiffs' conclusory allegation that the Federal Circuit would have affirmed Judge Broderick's decision invalidating the tamoxifen patent. *See Mason v. Am. Tobacco Co.*, 346 F.3d 36, 39 (2d Cir.2003) ("[L]egal conclusions, deductions or opinions couched as factual allegations are not given a presumption of truthfulness." (internal quotation marks and citations omitted)), *cert. denied*, 541 U.S. 1057, 124 S.Ct. 2163, 158 L.Ed.2d 757 (2004); *Smith v. Local 819 I.B.T. Pension Plan*, 291 F.3d 236, 240 (2d Cir.2002) ("[C]onclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss." (internal quotation marks and citation omitted)).

18. Indeed, our Circuit requires civil litigants to go through a pre-argument, Court-sponsored process called the Civil Appeals (Cont'd)

disputes, even antitrust and patent disputes of which an appeal is pending, in order to eliminate that risk, are not prohibited. That Zeneca had sufficient confidence in its patent to proceed to trial rather than find some means to settle the case first should hardly weigh against it.

We conclude, then, that without alleging something more than the fact that Zeneca settled after it lost to Barr in the district court that would tend to establish that the Settlement Agreement was unlawful, the assertion that there was a bar-antitrust or otherwise-to the defendants' settling the litigation at the time that they did is unpersuasive.

2. Reverse Payments. Payments pursuant to the settlement of a patent suit such as those required under the Settlement Agreement are referred to as "reverse" payments because, by contrast, "[t]ypically, in patent infringement cases the payment flows from the alleged infringer to the patent holder." David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 Food & Drug L.J. 321, 335 (2000). Here, the patent holder, which, if its patent is valid, has the right to prevent the alleged infringer from making commercial use of it, nonetheless pays that party not to do so. Seeking to

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Management Plan ("CAMP"), *see http://www.ca2.uscourts.gov/Docs/Forms/CAMP.pdf* and *http://www.ca2.uscourts.gov/Docs/Forms/Preargument.pdf*, designed in part to facilitate just such post-judgment, pre-appellate argument settlements-which it accomplishes with significant success. *See* Gilbert J. Ginsburg, *The Case for a Mediation Program in the Federal Circuit*, 50 Am. U. L.Rev. 1379, 1383 (2001) (reporting estimate that forty-five to fifty percent of civil cases pending before the Second Circuit settle each year).

supply the "something more" than the fact of settlement that would render the Settlement Agreement unlawful, the plaintiffs allege that the value of the reverse payments from Zeneca to Barr thereunder "greatly exceeded the value of Barr's 'best case scenario' in winning the appeal . . . and entering the market with its own generic product." Appellants' Br. at 27.

It is the size, not the mere existence, of Zeneca's reverse payment that the plaintiffs point to in asserting that they have successfully pleaded a Sherman Act cause of action. In explaining our analysis, though, it is worth exploring the notion advanced by others that the very existence of reverse payments establishes unlawfulness. *See* Balto, *supra*, at 335 ("A payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties in entering the agreement and the rent-preserving effect of that agreement."); Herbert Hovenkamp *et al.*, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L.Rev. 1719, 1751 (2003) ("[T]he problem of exclusion payments can arise whenever the patentee has an incentive to postpone determination of the validity of its patent.").

Heeding the advice of several courts and commentators, we decline to conclude (and repeat that the plaintiffs do not ask us to conclude) that reverse payments are *per se* violations of the Sherman Act such that an allegation of an agreement to make reverse payments suffices to assert an antitrust violation. We do not think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation. *See Valley Drug*, 344

F.3d at 1309 (concluding *390 that the presence of a reverse payment, by itself, does not transform an otherwise lawful settlement into an unlawful one); *Asahi Glass*, 289 F.Supp.2d at 994 (asserting that "[a] ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive," and observing that if the parties decided not to settle, and the patent holder ultimately prevailed in the infringement lawsuit, there would be the same level of competition as in the reverse payment case); Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 Minn. L.Rev. 1789, 1807 (2003) (stating that "the plaintiff often will have an incentive to pay the defendant not to enter the market, regardless of whether the former expects to win at trial," which "suggests that reverse payments should not be per se illegal, since they are just as consistent with a high probability of validity and infringement as they are with a low probability. It also suggests that reverse payments should not be per se legal for the same reason."). *But see Cardizem*, 332 F.3d at 911 (calling a forty-million-dollar reverse payment to a generic manufacturer "a naked, horizontal restraint of trade that is *per se* illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers").

As other courts have noted, moreover, reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them. *See Cipro II*, 261 F.Supp.2d at 252 (noting

that the Hatch-Waxman Act "has the unintended consequence of altering the litigation risks of patent lawsuits" and concluding that "reverse payments are a natural by-product of the Hatch-Waxman process"); *accord Schering-Plough*, 402 F.3d at 1074.

In the typical patent infringement case, the alleged infringer enters the market with its drug after the investment of substantial sums of money for manufacturing, marketing, legal fees, and the like. The patent holder then brings suit against the alleged infringer seeking damages for, *inter alia*, its lost profits. If the patent holder wins, it receives protection for the patent and money damages for the infringement. And in that event, the infringer loses not only the opportunity to continue in the business of making and selling the infringing product, but also the investment it made to enter the market for that product in the first place. And it must pay damages to boot. It makes sense in such a circumstance for the alleged infringer to enter into a settlement in which it pays a significant amount to the patent holder to rid itself of the risk of losing the litigation.

By contrast, under the Hatch-Waxman Act, the patent holder ordinarily brings suit shortly after the paragraph IV ANDA has been filed- *before* the filer has spent substantial sums on the manufacturing, marketing, or distribution of the potentially infringing generic drug. The prospective generic manufacturer therefore has relatively little to lose in litigation precipitated by a paragraph IV certification beyond litigation costs and the opportunity for future profits from selling the generic drug. Conversely, there are no infringement damages for the patent holder to recover, and there is therefore little

reason for it to pursue the litigation beyond the point at which it can assure itself that no infringement will occur in the first place.

Accordingly, a generic marketer has few disincentives to file an ANDA with a paragraph IV certification. The incentive, by contrast, may be immense: the profits it will likely garner in competing with the patent holder without having invested substantially in the development of the drug, and, in addition, possible entitlement to a 180-day period (to be triggered at its inclination) during which it would be the exclusive seller of the generic drug in the market.[19]

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19. In this case, Barr could not at the time of the Settlement Agreement count on obtaining the 180-day exclusive period from the FDA because, as a settler rather than a "successful defender," it at least appeared that it was unlikely to be entitled to the period of exclusivity-in other words, it appeared that, by settling, Barr was trading away its exclusivity period. It is noteworthy, nonetheless, that the 180-day period is of substantial benefit to the generic drug manufacturer who obtains it because it gives that manufacturer a significant head start over other manufacturers. *See, e.g., Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 494, 510 (2d Cir.2004) (considering claim that defendant's first-mover status converted a transitory advantage into a permanent one, where plaintiffs provided testimony that "even though its offer price to the Eckerd and CVS drugstore chains was as much as 25 percent below [the first mover's price], neither chain was willing to leave [the first mover] after having devoted substantial time to switching patients and getting their pharmacists comfortable with the new product"); *Mova Pharm.*, 955 F.Supp. at 131 ("All parties recognize that the earliest generic drug manufacturer in a specific market has a distinct advantage over later entrants.").

Appendix A

The patent holder's risk if it loses the resulting patent suit is correspondingly large: It will be stripped of its patent monopoly. At the same time, it stands to gain little from winning other than the continued protection of its lawful monopoly over the manufacture and sale of the drug in question.

"Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, [the generic challengers] gain[ ] considerable leverage in patent litigation: the exposure to liability amount[s] to litigation costs, but pale[s] in comparison to the immense volume of generic sales and profits." *Schering-Plough*, 402 F.3d at 1074 (citation omitted).

Under these circumstances, we see no sound basis for categorically condemning reverse payments employed to lift the uncertainty surrounding the validity and scope of the holder's patent.[20]

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20. It has been observed that even the typical settlement of the ordinary patent infringement suit appears to involve what may be characterized as a reverse payment. *See Cipro II*, 261 F.Supp.2d at 252 ("[E]ven in the traditional context, implicit consideration flows from the patent holder to the alleged infringer."); *cf. Asahi Glass*, 289 F.Supp.2d at 994 ("*[A]ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." (emphasis in original)); Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 Minn. L.Rev. 698, 700

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Appendix A

3. "Excessive" Reverse Payments. As we have noted, although there are those who contend that reverse payments are in and of themselves necessarily unlawful, the plaintiffs are not among them. They allege instead that "[t]he value of the consideration provided to keep Barr's product off the market . . . greatly exceeded the value Barr could have realized by successfully defending its trial victory on appeal and entering the market with its own competitive generic product." Appellants' Br. at 15. The plaintiffs assert that it is that excessiveness that renders the Settlement Agreement unlawful.[21] We agree that even if "reverse payments are a natural by-product of the Hatch-Waxman process," *Cipro II*,

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(2004) ("It makes no sense to single out exclusion payments for disfavor when the same potential for collusion arises in any settlement involving the defendant's exit."). A blanket rule that all settlements involving reverse payments are unlawful could thus conceivably endanger many ordinary settlements of patent litigation.

21. The Federal Trade Commission and some commentators have proposed similar or even more stringent rules. *See In re Schering-Plough Corp.*, 2003 WL 22989651 , 2003 FTC LEXIS 187 (Dec. 8, 2003) (applying a rule under which generic manufacturers would not be permitted to receive reverse payments that exceeded "the lesser of the [patent] [h]older's expected future litigation costs to resolve the Patent Infringement Claim or $2 million"), *vacated*, 402 F.3d 1056 (11th Cir.2005); Hovenkamp *et al.*, *supra*, at 1759 (proposing that "[i]n an antitrust challenge, a payment from a patentee to an infringement defendant for the latter's exit from the market is presumptively unlawful," and that the "infringement plaintiff can defend by showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit").

261 F.Supp.2d at 252, it does not follow that they are necessarily lawful, *see* Hovenkamp *et al.*, *supra*, at 1758 ("We do not think it follows that because it is rational for the patentee to agree to an exclusion payment, that payment cannot be anticompetitive. Far from it."). But

> [o]nly if a patent settlement is a device for circumventing antitrust law is it vulnerable to an antitrust suit. Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices-masks-for fixing prices, in violation of antitrust law.

Asahi Glass, 289 F.Supp.2d at 991. "If, however, there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation." *Id.* at 992.

There is something on the face of it that does seem "suspicious" about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn by winning the lawsuit and entering the newly competitive market in competition with the patent

holder. Why, after all-viewing the settlement through an antitrust lens-should the potential competitor be permitted to receive such a windfall at the ultimate expense of drug purchasers? We think, however, that the suspicion abates upon reflection. In such a case, so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.[22]

If the patent holder loses its patent monopoly as a result of defeat in patent litigation against the generic manufacturer, it will likely lose some substantial portion of the market for the drug to that generic manufacturer and perhaps others.

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22. The dissent questions what it sees as our reliance on the presumption of validity of the patent at the time of the settlement. Even after a district court holds a patent invalid, it is treated as presumptively valid under 35 U.S.C. § 282 on appeal. *See Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1377-78 (Fed.Cir.2002). But irrespective of whether there was a presumption or where any such presumption lay at the time of settlement, we think that Zeneca was then entitled to protect its tamoxifen patent monopoly through settlement. The question for this Court is whether the settlement extended the patent's scope. If the judgment of the district court against a patent's validity put an end to the patent monopoly that the patent holder was entitled to protect, then *any* settlement after judgment of the district court holding the patent invalid would extend the patent monopoly beyond the patent's scope and therefore be unlawful. We do not think that to be the law, a view which appears to be consistent with the plaintiffs'. *See* Appellants' Reply Br. at 4, Heading "B." ("Hatch-Waxman Patent Infringement Litigation Can Be Settled, Even On Appeal, Without Violating The Antitrust Laws.").

The patent holder might also (but will not necessarily)[23] lower its price in response to the competition. The result will be, unsurprisingly, that (assuming that lower prices do not attract significant new purchasers for the drug) the *total* profits of the patent holder and the generic manufacturer on the drug in the competitive market will be *lower* than the total profits of the patent holder alone under a patent-conferred monopoly. In the words of the Federal Trade Commission: "The anticipated profits of the patent holder in the absence of generic competition are greater than the sum of its profits and the profits of the generic entrant when the two compete." *In re Schering-Plough Corp.*, 2003 WL 22989651 (Dec. 8, 2003), 2003 FTC LEXIS 187, *vacated*, 402 F.3d 1056 (11th Cir.2005). It might therefore make economic sense for the patent holder to pay some portion of that difference to the generic manufacturer to maintain the patent-monopoly market for itself. And, if that amount exceeds what the generic manufacturer sees as its likely profit from victory, it seems to make obvious economic sense for the generic manufacturer to accept such a payment if it is offered.[24] We think we can

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23. There is authority for the proposition that when its patent monopoly is ended, the patent holder might actually *raise* the price on its branded product, rather than lower it in response to generic competition. *See* Congr. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 29-31 (July 1998), *available at* http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf (last visited May 12, 2005).

24. To illustrate using a vastly oversimplified hypothetical example (ignoring, for example, legal fees and costs): Suppose the patent holder is selling 1,000,000 pills per year at a $1 profit per pill

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safely assume that the patent holder will seek to pay less if it can, but under the circumstances of a paragraph IV Hatch-Waxman filing, as we have discussed, the ANDA filer might well have the whip hand. *Cf. Valley Drug*, 344 F.3d at 1310 ("Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.").

Of course, the law could provide that the willingness of the patent holder to settle at a price above the generic

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(for a total profit of $1,000,000). The generic manufacturer files a paragraph IV ANDA, and the patent holder responds by bringing suit to protect its patent. If the patent holder projects that, should it lose the suit, it will thereafter sell only 250,000 pills per year at a $.90 profit per pill (for a total profit of $225,000) in the competitive market, and the generic will sell 750,000 pills per year at a profit of $.60 per pill (for a total profit of $450,000)-so that total market profits are now down from $1,000,000 to $675,000-it would make economic sense for the patent holder to pay the generic manufacturer something more than the $450,000 the generic manufacturer would make in a competitive market to settle the litigation. If it paid $500,000 a year to the generic manufacturer-$50,000 more than the generic manufacturer could earn in the market in a "best case scenario"-for example, it would thereby retain the ability to make $500,000 per year selling its branded pills ($1,000,000 profit less $500,000 per year paid to the generic), $275,000 *more* per year than it would earn if it paid nothing to the generic but lost the patent litigation and with it the patent monopoly. It might well be sensible for the patent holder to enter into this sort of settlement, depending in part on its perceived prospects for winning the litigation, and it would seem difficult for the generic manufacturer to refuse. The $325,000 of yearly monopoly profits which accrued to the patent holder before the litigation began would thereafter be divided between the patent holder and the generic manufacturer.

manufacturer's projected profit betrays a fatal disbelief in the validity of the patent or the likelihood of infringement, and that the patent holder therefore ought not to be allowed to maintain its monopoly position. Perhaps it is unwise to protect patent monopolies that rest on such dubious patents. But even if large reverse payments indicate a patent holder's lack of confidence in its patent's strength or breadth, we doubt the wisdom of deeming a patent effectively invalid on the basis of a patent holder's fear of losing it.

> [T]he private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case. A firm that has received a patent from the patent office (and not by fraud . . .), and thus enjoys the presumption of validity that attaches to an issued patent, 35 U.S.C. § 282, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment. It is not "bad faith" to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights. No one can be *certain* that he will prevail in a patent suit.

Asahi Glass, 289 F.Supp.2d at 992-93 (citation omitted) (emphasis in original).

Such a rule would also fail to give sufficient consideration to the patent holder's incentive to settle the lawsuit without reference to the amount the generic manufacturer might earn in a competitive market, even when it is relatively confident of the validity of its patent-to insure against the possibility that its confidence is misplaced, or, put another way, that a reviewing court might (in its view) render an erroneous decision. *Cf. Schering-Plough*, 402 F.3d at 1075-76. Whatever the degree of the patent holder's certainty, there is always some risk of loss that the patent holder might wish to insure against by settling.

This case is illustrative. It is understandable that however sure Zeneca was at the outset that its patent was valid, settlement might have seemed attractive once it lost in the district court, especially in light of the deferential standard the Federal Circuit was expected to apply on review. But its desire to settle does not necessarily belie Zeneca's confidence in the patent's validity. Indeed, Zeneca's pursuit of subsequent litigation seeking to establish the tamoxifen patent's validity, and the success of that litigation, strongly suggest that such confidence persisted and was not misplaced. Neither do we think that the settlement's entry after the district court rendered a judgment against Zeneca should counsel against the settlement's propriety. It would be odd to handicap the ability of Zeneca to settle after it had displayed sufficient confidence in its patent to risk a finding of invalidity by taking the case to trial.

We are unsure, too, what would be accomplished by a rule that would effectively outlaw payments by patent holders to generic manufacturers greater than what the latter would

be able to earn in the market were they to defend successfully against an infringement claim. A patent holder might well prefer such a settlement limitation-it would make such a settlement cheaper-while a generic manufacturer might nonetheless agree to settle because it is less risky to accept in settlement all the profits it expects to make in a competitive market rather than first to defend and win a lawsuit, and then to enter the marketplace and earn the profits. If such a limitation had been in place here, Zeneca might have saved money by paying Barr the maximum such a rule might allow-what Barr was likely to earn if it entered the market-and Barr would have received less than it could have if it were free to negotiate the best deal available-as it did here. But the resulting level of competition, and its benefit to consumers, would have been the same. The monopoly would have nonetheless endured-but, to no apparent purpose, at less expense to Zeneca and less reward for Barr.

It strikes us, in other words, as pointless to permit parties to enter into an agreement settling the litigation between them, thereby protecting the patent holder's monopoly even though it may be based on a relatively weak patent, but to limit the amount of the settlement to the amount of the generic manufacturer's projected profits had it won the litigation.

We are not unaware of a troubling dynamic that is at work in these cases. The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent. But the law allows the settlement even of suits involving weak patents with the

presumption that the patent is valid and that settlement is merely an extension of the valid patent monopoly. So long as the law encourages settlement, weak patent cases will likely be settled even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved.

We also agree with the *Cipro III* court's observation that:

> If courts do not discount the exclusionary power of the patent by the probability of the patent's being held invalid, then the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity. This concern, on its face, is quite powerful. But the answer to this concern lies in the fact that, while the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid.

Cipro III, 363 F.Supp.2d at 534. There is, of course, the possibility that the patent holder will continue to buy out potential competition such that a settlement with one generic manufacturer protecting the patent holder's ill-gotten patent monopoly will be followed by other settlements with other generic manufacturers should a second, third, and fourth rise to challenge the patent. We doubt, however, that this scenario is realistic.

Appendix A

Every settlement payment to a generic manufacturer reduces the profitability of the patent monopoly. The point will come when there are simply no monopoly profits with which to pay the new generic challengers. "[I]t is unlikely that the holder of *396 a weak patent could stave off *all* possible challengers with exclusion payments because the economics simply would not justify it." *Cipro III*, 363 F.Supp.2d at 535 (emphasis supplied). We note in this regard that Zeneca settled its first tamoxifen lawsuit against the first generic manufacturer, Barr, but did not settle, and, as far as we know, did not attempt to settle, the litigation it brought against the subsequent challenging generics, Novopharm, Pharmachemie, and Mylan. (To be sure, the settlement with Barr came after a judgment *against* Zeneca, while the judgments in Novopharm, Pharmachemie, and Mylan's challenges were *for* Zeneca.)[25]

An alternative rule is, of course, possible. As suggested above, the antitrust laws could be read to outlaw all, or nearly all, settlements of Hatch-Waxman infringement actions. Patent holders would be required to litigate each threatened patent to final, unappealable judgment. Only patents that the

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25. It seems to us odd for the dissent to urge, in the context of this case, that we have not given proper weight to "the public interest in having the validity of patents litigated." The Settlement Agreement was a virtual invitation to other generic manufacturers to file paragraph IV certifications and thereby court litigation as to the validity of the tamoxifen patent. It was an invitation that was accepted three times leading to three lawsuits, two of them litigated to judgment, as to the validity of the tamoxifen patent. Accepting the value of litigating the validity of patents in these circumstances, it has hardly been undermined here.

courts held were valid would be entitled to confer monopoly power on their proprietors. But such a requirement would be contrary to well-established principles of law. As we have rehearsed at some length above, settlement of patent litigation is not only suffered, it is encouraged for a variety of reasons even if it leads in some cases to the survival of monopolies created by what would otherwise be fatally weak patents. It is too late in the journey for us to alter course.[26]

We generally agree, then, with the Eleventh Circuit insofar as it held in *Valley Drug* that " 'simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law,' unless the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection.' " *Cipro III*, 363 F.Supp.2d at 538 (quoting *Schering-Plough*, 402 F.3d at 1076 (alteration omitted)). Whatever damage is done to competition by settlement is done pursuant to the monopoly extended to the patent holder by patent law unless the terms of the settlement enlarge the scope of that monopoly. "Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement

26. The dissent "see[s] no reason why the general standard for evaluating an anti-competitive agreement, i.e., its reasonableness, should not govern in this context." We think, such a rule, making every settlement of patent litigation, at least in the Hatch-Waxman Act context, subject to the inevitable, lengthy and expensive hindsight of a jury as to whether the settlement constituted a "reasonable" restraint (and, in this case, whether the Federal Circuit would have affirmed or reversed in a patent appeal), would place a huge damper on such settlements contrary to the law that we have discussed at some length that settlements are not only permitted, they are to be encouraged.

is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." *Cipro III*, 363 F.Supp.2d at 535.

We further agree with the *Cipro III* court that absent an extension of the monopoly beyond the patent's scope, an issue that we address in the next section of this *397 opinion, and absent fraud, which is not alleged here, the question is whether the underlying infringement lawsuit was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993).[27] In this

27. The reasoning of the dissent, which quotes an excerpt from this statement, is, in our view, largely based on a repeated mischaracterization of our views in this regard. We do not, as the dissent states in one form or another many times, think that there is a "requirement" that antitrust plaintiffs "must show that the settled litigation was a sham, i.e., objectively baseless, before the settlement can be considered an antitrust violation . . . ,". There is no such requirement. The central criterion as to the legality of a patent settlement agreement is whether it "exceeds the 'scope of the patent's protection.' " As we pointed out at the outset of this discussion, we think that "[i]f the plaintiffs alleged facts that, if proved, would establish that the Settlement Agreement provided the defendants with benefits exceeding the scope of the tamoxifen patent, they would succeed in alleging an antitrust violation." ("[T]he question is whether the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection.' *Schering-Plough*, 402 F.3d at 1076."). A plaintiff need not allege or prove sham litigation in order to succeed in establishing that a settlement has provided defendants "with

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case, the plaintiffs do not contend that they can-and we conclude that in all likelihood they cannot-establish that Zeneca's patent litigation was baseless, particularly in light of the subsequent series of decisions upholding the validity of the same patent. *Cf. id.* at 60 n. 5, 113 S.Ct. 1920 ("A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham."). Payments, even "excessive" payments, to settle the dispute were therefore not necessarily unlawful.

4. The Terms of the Settlement Agreement. Inasmuch as we conclude that neither the fact of settlement nor the amount of payments made pursuant thereto as alleged by the plaintiffs would render the Settlement Agreement unlawful, we must assess its other terms to determine whether they do. As we have explained in the previous section of this opinion, we think that the question is whether the "exclusionary effects of the agreement" exceed the "scope of the patent's protection." *Schering-Plough*, 402 F.3d at 1076. Looking to other courts that have addressed similar cases for guidance, and accepting the plaintiffs' allegations as true, we conclude that the Settlement Agreement did not unlawfully extend the reach of Zeneca's tamoxifen patent.

First, the Settlement Agreement did not extend the patent monopoly by restraining the introduction or marketing of unrelated or non-infringing products. It is thus unlike the

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benefits exceeding the scope of the tamoxifen patent." Whether there is fraud or baseless litigation may be relevant to the inquiry, but it is hardly, we think, "the . . . standard," as the dissent posits in order to take issue with it.

agreement the Sixth Circuit held *per se* illegal in *Cardizem*, 332 F.3d at 908, which included not only a substantial reverse payment but also an agreement that the generic manufacturer would not market non-infringing products. *See id.* at 902, 908 & n. 13 (quoting the court in *Cipro II*, 261 F.Supp.2d at 242, which observed that the *Cardizem* district court, in condemning the settlement agreement in that case, " 'emphasized that the agreement [there] restrained Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation, ... Thus, the court found that the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem.' " (alterations in original)); *see also Valley Drug*, 344 F.3d at 1306 n. 18 (observing that if the agreement "also prohibited the marketing of non-infringing terazosin products, prohibited [the generic manufacturer] from marketing infringing products beyond the date a district court held the [relevant] patent invalid, and prohibited [the generic manufacturer] from waiving its 180-day exclusivity period" then the agreement "may be beyond the scope of [the patent holder's] lawful right to exclude and, if so, would expose appellants to antitrust liability"); *In re K-Dur Antitrust Litig.*, 338 F.Supp.2d 517, 532 (D.N.J.2004) (noting, in connection with a private lawsuit involving the same settlement agreements challenged by the FTC in *Schering-Plough*, that the plaintiffs "alleged that [the generic manufacturer] not only agreed not to enter the market with the allegedly infringing generic drug at issue in the patent litigation, but agreed not to enter the market with *any* generic competitor drug, irrespective of whether it infringed the patent" and that another potential distributor of generic equivalents also agreed to delay marketing a

generic competitor drug and "agreed not to conduct, sponsor, file or support any study of a generic drug's bioequivalence to [the patented drug] before the expiration of the [relevant] patent," and concluding: "These agreements, as alleged, grant rights to Schering in excess of what is granted by the [relevant] patent alone." (emphasis in original)).

Like the patent for the compound ciprofloxacin hydrochloride, which was the subject of dispute in the *Cipro* cases, and unlike the patents at issue in *Cardizem* and *Valley Drug*, Zeneca's tamoxifen patent is not a formulation patent, which covers only specific formulations or delivery methods of compounds; rather, it is a patent on a compound that, by its nature, excludes all generic versions of the drug. *See* Appellees' Br. at 23; *Cipro II*, 261 F.Supp.2d at 249-50 (observing that the patent in that case covered all formulations and the generic manufacturer could not have avoided it). Because Zeneca's patent therefore precludes all generic versions of tamoxifen, so that any such competing version would, as we understand it, necessarily infringe the patent, the Settlement Agreement did not, by precluding the manufacture of a generic version of tamoxifen, restrain the marketing of any non-infringing products.

Second, the Settlement Agreement ended all litigation between Zeneca and Barr and thereby opened the tamoxifen patent to immediate challenge by other potential generic manufacturers, which did indeed follow-spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit, since by vacating the district court judgment, Barr ensured (under procedures in

effect at the time) that it was not eligible for the exclusivity period. *See Cipro II*, 261 F.Supp.2d at 242-43 (emphasizing that the settlement in that case extinguished the litigation between Barr and Bayer and that Barr thereby relinquished its claim to the 180-day exclusivity period, thus removing any "bottleneck" to future generic entrants). The Agreement thus avoided a "bottleneck" of the type created by the agreements in *Valley Drug* and *Cardizem*, which prevented other generic manufacturers from obtaining approval for their own generic versions from the FDA. Rather than resolve the litigation, the settlements in those cases prolonged it by providing incentives to the defendant generic manufacturers not to pursue the litigation avidly. In *Cardizem*, for example, the settlement included periodic payments to the generic manufacturer during the pendency of the lawsuit in exchange for its promise not to market a generic drug for *399 which it had already received FDA approval, thereby delaying the market entry of other generic manufacturers "who could not enter until the expiration of [the first-moving generic manufacturer's] 180-day period of marketing exclusivity, which [the generic] had agreed not to relinquish or transfer." *Cardizem*, 332 F.3d at 907; *see also Cipro II*, 261 F.Supp.2d at 243 (noting that in *Valley Drug*, the generic manufacturer had obtained final FDA approval, yet the settlement agreement "delayed triggering [the generic manufacturer's] 180-day exclusivity period, effectively holding up FDA approval of other generic manufacturers' ANDA IVs.").

The disadvantage purportedly suffered by the plaintiffs is not that Barr somehow prevented others from challenging the patent and obtaining FDA approval; nor is it that no other generic manufacturer tried to do so. It is instead that each of

the subsequent challenges failed. While it is true that, had the district court's decision in Zeneca's patent infringement lawsuit against Barr been affirmed, other generic manufacturers would have been allowed to market their drugs, there is no legal requirement that parties litigate an issue fully for the benefit of others. *See, e.g., Nestle*, 756 F.2d at 284.

Thus the stated terms of the Settlement Agreement include nothing that would place it beyond the legitimate exclusionary scope of Zeneca's patent: The Settlement Agreement did not have an impact on the marketing of non-infringing or unrelated products, and the Agreement fully resolved the litigation between Zeneca and Barr, clearing the way for other generic manufacturers to seek to enter the market.

Finally, the Settlement Agreement did not entirely foreclose competition in the market for tamoxifen. It included a license from Zeneca to Barr that allowed Barr to begin marketing Zeneca's version of tamoxifen eight months after the Settlement Agreement became effective. The license ensured that money also flowed from Barr to Zeneca, decreasing the value of the reverse payment. By licensing tamoxifen to Barr, Zeneca added a competitor to the market, however limited the competition may have been. Unlike reverse payment settlements that leave the competitive situation as it was prior to the litigation,[28] the reverse payment

28. *See Asahi Glass*, 289 F.Supp.2d at 994 (noting that in the typical reverse-payment case, "the settlement leaves the competitive situation unchanged from before the defendant tried to enter the market.").

in this case was pursuant to an agreement that increased competition in the market for tamoxifen-even if only a little-almost nine years before the tamoxifen patent was to expire. *Cf. Cipro II*, 261 F.Supp.2d at 209 (noting that if the patent holder had not agreed to pay the generic manufacturers "hundreds of millions of dollars," then the patent holder "would have issued to [the generic manufacturers] a license for distribution of generic Cipro").

The Settlement Agreement almost certainly resulted in less price competition than if Barr had introduced its own generic version, of course. The plaintiffs allege that the Barr-distributed, Zeneca-manufactured tamoxifen sold at retail for just five percent less than the Zeneca-branded version, Compl. ¶ 75, compared with what the plaintiffs allege is a typical initial drop of sixteen percent or more, *see* Oral Argument Tr., July 12, 2004, at 5, and an eventual drop in a truly competitive market of thirty to eighty percent, Compl. ¶ 75. *See also* Congr. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 32 (July *400 1998), *available at* http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf (last visited May 12, 2005) (describing one study that estimated that the average price of a generic drug fell from sixty percent of the brand-name price to thirty-four percent of the brand-name price as the number of generic manufacturers increased from one to ten). This was competition nonetheless. It was certainly more competition than would have occurred had there been no settlement and had Zeneca prevailed on appeal. *Cf. Nestle*, 756 F.2d at 284 (noting that the district court erred by not placing more weight on the consequences of requiring the litigation to go forward,

such as the fact that "the appellees will be forced to bear the costs and risks of further litigation, including the non-trivial risk of a reversal on the merits").

We conclude that the facts as alleged in the plaintiffs' complaint, if proved, would not establish that the terms of the Settlement Agreement violated the antitrust laws. In the absence of any plausible allegation that the reverse payment provided benefits to Zeneca outside the scope of the tamoxifen patent, the plaintiffs have not stated a claim for relief with respect to the Settlement Agreement. *See Twombly*, 425 F.3d at 111.

5. Barr's 180-Day Exclusivity Period. The plaintiffs also advance allegations regarding actions that Barr took with respect to the 180-day exclusivity period to which the first paragraph IV filer is entitled under the Hatch-Waxman Act. We confess that it is not altogether clear to us what the import of those allegations is. The plaintiffs contend that Barr's attempt to assert its exclusivity period in 1998, five years after the date of the Settlement Agreement, should be viewed as "circumstantial evidence demonstrating the anticompetitive consequences of [the] agreement[ ]" among the defendants. Appellants' Reply Br. at 13. They allege that the Settlement Agreement was drafted "careful[ly] to preserve Barr's" ability to "strategically deploy[ ]" its claim to the exclusivity period. Compl. ¶ 57. And they further allege the existence of an understanding among the defendants as to when and under what circumstances "Barr would assert its claimed exclusivity period rights to prevent . . . FDA approval" of other generic manufacturers' ANDA applications, "even if Zeneca was unsuccessful in using

patent litigation to keep another generic competitor off the market."[29] *Id.* ¶ 58. They also contend that because they have alleged an unlawful conspiracy, the issue is only "whether Barr's conduct in blocking generic entry was in furtherance of that alleged conspiracy." Appellants' Br. at 35 (emphasis omitted).

The defendants contend in response that any consequences of the 180-day exclusivity period resulted from Barr's petition to the FDA, and that Barr's actions in claiming the 180-day exclusivity period were therefore immune from antitrust scrutiny under the *Noerr-Pennington* doctrine, which immunizes parties from antitrust liability for injuries resulting from government action prompted by the parties' petitioning activities. *See E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961) (stating that "the Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive [or an agency or a court] to take particular action with respect to a law that would produce a restraint or a monopoly"); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965) ("Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition."). Such immunity does not disappear even if the petitioning activity is intended to harm competitors. *See Noerr*, 365 U.S. at 138-39, 81 S.Ct. 523. In this case, the defendants assert, because Barr's petitioning activity was protected under *Noerr-Pennington*, it cannot be the basis for antitrust liability.

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29. Of course, as it turned out, Zeneca *was* successful in subsequently protecting its patent in the courts.

We are not so sure. Although *Noerr-Pennington* immunity may lend Barr's actions some protection, it does not immunize all actions with respect to the 180-day exclusivity period from antitrust scrutiny. The doctrine does not extend protection to the defendants "where the alleged conspiracy 'is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.' " *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 511, 92 S.Ct. 609, 30 L.Ed.2d 642 (1972) (quoting *Noerr*, 365 U.S. at 144, 81 S.Ct. 523). And it "does not authorize anticompetitive *action* in advance of [the] government's adopting the industry's anticompetitive proposal. The doctrine applies when such action is the consequence of legislation or other governmental action, not when it is the means for obtaining such action." *In re Brand Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781, 789 (7th Cir.1999) (emphasis in original); *see also Juster Assocs. v. City of Rutland*, 901 F.2d 266, 271-72 (2d Cir.1990) (stating that when a claimed restraint is the consequence of government action, it falls within the purview of *Noerr-Pennington* immunity, but when the restraint is the means by which the defendants seek to obtain favorable government action, it does not). Because we think that an agreement to time the deployment of the exclusivity period to extend a patent's monopoly power might well constitute anticompetitive action outside the scope of a valid patent, we decline to rest our conclusion on the ground of *Noerr-Pennington* immunity.[30]

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30. "The competitive concern is that the 180-day exclusivity provision can be used strategically by a patent holder to prolong its market power in ways that go beyond the intent of the patent laws

(Cont'd)

We nonetheless do not think that the facts as alleged with respect to Barr's claim to the 180-day exclusivity period amount to an antitrust violation.

First, as we have explained, our review of the Settlement Agreement convinces us that, accepting the plaintiffs' allegations as true, the defendants did not violate the antitrust laws merely by entering into it. Therefore, even if we were to view Barr's actions with regard to the 180-day exclusivity period as somehow constituting "evidence"–"circumstantial" or otherwise-of the "anticompetitive consequences" of the Settlement Agreement, it would not affect our conclusion. The Agreement is no doubt "anticompetitive"-the plaintiffs need no additional proof of that. It limited competition between generic tamoxifen and Zeneca's branded product. But, as we have seen, because it did not exceed the scope of the tamoxifen patent, it was not an *unlawful* anticompetitive agreement.

(Cont'd)

and the Hatch-Waxman Act by delaying generic entry for a substantial period." Balto, *supra*, at 331. An agreement that a "generic manufacturer would not relinquish its 180-day exclusivity . . . prevent[s] other generic manufacturers from entering as well." *Id.* at 335; *see also* Hovenkamp *et al.*, *supra*, at 1755 ("It is widely understood that the 180-day exclusivity period offers the potential for collusive settlement arrangements between pioneers and generics. A pioneer could initiate a patent infringement suit against a first generic ANDA filer and settle the litigation with a 'non-entry' payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market indefinitely.").

Second, because we have concluded that the Settlement Agreement was not itself an unlawful conspiracy, Barr's "block[ing of] generic entry" would not be unlawful as "in furtherance of" an unlawful conspiracy. There would have to *be* an unlawful conspiracy before Barr's actions could contribute to it.

Third, [t]he factual predicate that is pleaded does need to include [an unlawful] conspiracy among the realm of plausible possibilities. *Twombly*, 425 F.3d at 111 (footnote omitted). Assuming that the plaintiffs intended to allege a separate agreement among the defendants relating to Barr's manipulation of its exclusivity period in order to protect the defendants from competition from other generic manufacturers, the pleaded conspiracy seems to us to be "implausible."

At the time the Settlement Agreement was entered into, the established law was that a generic manufacturer must "successfully defend" a patent infringement lawsuit in order to obtain exclusivity.[31] Accordingly, even if Barr might have

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31. In *Andrx*, the defendant attempted unsuccessfully to claim that it was unable to cause any delay in generic entry because the "successful defense" requirement would prevent it from doing so. *Andrx Pharms.*, 256 F.3d at 810. The D.C. Circuit noted that the settlement agreement in that case was signed in September 1997-after the district court in *Mova* issued, in January 1997, a preliminary injunction banning the enforcement of the successful defense requirement. *Id.* (citing *Mova Pharm.*, 955 F.Supp. at 131-32). Thus, "[t]he timing of the Agreement and of the demise of the successful defense requirement defeats Andrx's argument on this point." *Id.* In the instant case, however, the Settlement Agreement was executed long before *Mova* struck down the successful defense requirement.

suspected that the FDA would drop its "successful defense" requirement, it had, at the time, no claim to the exclusionary period. Although the Agreement in this case did include a provision allowing Barr to revert its paragraph III certification back to a paragraph IV certification in the event another generic manufacturer successfully invalidated the patent, it seems farfetched, in light of the law at the time, to construe that provision as a conscious and unlawful attempt to manipulate the exclusivity period.

Moreover, the fact that Barr acted as it did with respect to the deployment of the exclusionary period is easily explained by Barr's own interest in protecting itself from competition through a petition to the FDA for a statutorily prescribed benefit. Nothing that we can draw from the facts alleged in the complaint indicates how Barr's actions in this regard suggest that it was in league with Zeneca.[32]

Fourth and last, we have grave doubt as to whether, even if the defendants agreed to deploy the exclusionary period to protect their shared monopoly power, the injury that the defendants allege they suffered in this regard constitutes "antitrust injury."

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32. The dissent says that a reasonable fact-finder might conclude that sophisticated parties would not have included a provision that allowed Barr to re-file under paragraph IV absent an unlawfully anticompetitive purpose because it "had no potential benefit to either of them" apart from an anti-competitive one. We disagree. If another generic manufacturer had been successful in having the tamoxifen patent held invalid, it was strongly and legitimately in Barr's interest to be able to re-file so that it could market tamoxifen without risking a violation of the Settlement Agreement.

Appendix A

To state a claim under the Sherman Act, a plaintiff, in addition to stating an antitrust violation, must allege facts sufficient to prove that it suffered "antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977) (emphasis omitted); *see also George Haug Co., Inc. v. Rolls Royce Motor Cars Inc.*, 148 F.3d 136, 139 (2d Cir.1998). "The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." *Brunswick*, 429 U.S. at 489, 97 S.Ct. 690. "Harm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact." *Associated Gen. Contractors, Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 535 n. 31, 103 S.Ct. 897, 74 L.Ed.2d 723 (1983).

Accepting for the sake of argument that the plaintiffs have stated an antitrust violation by alleging an agreement or understanding between Barr and Zeneca to manipulate the 180-day exclusivity period, we are inclined to agree with the district court's conclusion that any injury that the plaintiffs suffered nonetheless resulted from Zeneca's valid patent and from the inability of other generic manufacturers to establish that the patent was either invalid or not infringed-and not from any agreement between Barr and Zeneca that Barr should employ its exclusivity powers to exclude competition. *See Tamoxifen II*, 277 F.Supp.2d at 136-38.

As we have noted, at the time that Zeneca and Barr entered into the Settlement Agreement and caused the district

court's judgment of patent invalidity to be vacated, Barr was not entitled to the 180-day period of exclusivity. It was only after the FDA announced that it was abandoning the "successful defense" requirement that Barr asserted its claim to the exclusivity period. *See Tamoxifen II*, 277 F.Supp.2d at 135. As the district court noted:

> Barr did *not* seek similar relief when Novopharm filed its ANDA and challenged the [tamoxifen] patent between 1994 and 1997. Only after the events in 1997 and 1998 . . . did Barr attempt to assert its rights. If Barr intended to protect its exclusivity period on behalf of itself and Zeneca *pursuant to the Settlement Agreement*, Barr's inactivity during the pendency of the Novopharm litigation is inexplicable.

Id. at 134 n. 9 (emphasis in original).

Therefore, the plaintiffs could not have suffered any antitrust injury with regard to an exclusivity period for Barr from the time the defendants signed the Settlement Agreement until the time the regulations were changed in 1997-1998. During that period, as far as all parties were concerned, the Settlement Agreement had indeed "cleared the field" so that other generic challengers could enter the market. Accordingly, any injury suffered by the plaintiffs during that time period was the result of Zeneca's legitimate patent monopoly-which remained intact as a result of the lawful Settlement Agreement-and not the result of any steps that Barr took.

The plaintiffs also suffered no antitrust injury from the time the "successful defense" requirement was eliminated until, in 2000, the FDA rejected Barr's claim to the exclusivity period, because the other ANDA filers with a paragraph IV certification ultimately lost their infringement suits against Zeneca. Even if Barr had not successfully petitioned the FDA, other generic manufacturers would not have been *404 able to enter the market with their generic versions without infringing the tamoxifen patent. As the district court rightly noted, this allegation of injury is "based on the lack of competition that could have only existed by illegally infringing on the [tamoxifen p]atent." *Id.* at 137-38. Thus, the plaintiffs did not suffer antitrust injury then either. *See, e.g., Axis, S.p.A. v. Micafil, Inc.*, 870 F.2d 1105, 1111 (6th Cir.), *cert. denied*, 493 U.S. 823, 110 S.Ct. 83, 107 L.Ed.2d 49 (1989) (finding no antitrust injury where plaintiffs had stated an antitrust violation, but where the alleged injury would have resulted even in the absence of the antitrust violation, because of the existence of patents preventing market entry).

Finally, there is clearly no antitrust injury with regard to Barr's use of the exclusivity period after the FDA rejected Barr's claim to the exclusivity period in 2000. From that time on, no one could have thought that Barr had a claim to an exclusivity period. Any injury suffered by the plaintiffs arose from Zeneca's patent monopoly, which remained valid until its expiration in 2002, after which other generic manufacturers did, in fact, enter the market.

For the foregoing reasons, we conclude that the plaintiffs have not sufficiently stated an antitrust claim arising out of

the defendants' actions with regard to Barr's 180-day exclusionary period.

IV. Leave To Amend

The plaintiffs contend that the district court erred in not addressing, and therefore in effectively denying, their request to amend their complaint to state a claim on which relief could be granted. The defendants reply that the district court acted within its discretion in effectively denying the plaintiffs' request-which appeared in a footnote in the middle of their brief opposing the defendants' motion to dismiss-because the request was buried and because it was, in any event, futile.

Federal Rule of Civil Procedure 15(a) provides that "a party may amend the party's pleading . . . by leave of court . . . and leave shall be freely given when justice so requires." A district court has broad discretion to decide whether to grant leave to amend, a decision that we review for an abuse of discretion. *Gurary v. Winehouse*, 235 F.3d 792, 801 (2d Cir.2000). It is within the court's discretion to deny leave to amend implicitly by not addressing the request when leave is requested informally in a brief filed in opposition to a motion to dismiss. *See id.* Furthermore, where amendment would be futile, denial of leave to amend is proper. *See Van Buskirk v. N.Y. Times Co.*, 325 F.3d 87, 91-92 (2d Cir.2003).

The plaintiffs' assertion that, if granted leave to amend, they "would be able to redress perceived deficiencies" in their complaint, Appellants' Br. at 56, does not persuade us. Even were plaintiffs to allege-as they now assert they are able to—that the defendants were concerned about the

possibility that the Settlement Agreement might run afoul of antitrust law, or that the reverse payments were in excess of Zeneca's litigation costs but "less than the substantial losses Zeneca anticipated upon generic competition," or that the defendants "believed the Federal Circuit would likely affirm" the invalidation of the tamoxifen patent, *id.*, in the absence of any plausible allegation that Zeneca's patent infringement lawsuit was baseless or that the Settlement Agreement otherwise restrained competition beyond the scope of the tamoxifen patent, their complaint would fail to state a claim on which relief can be granted.

"[I]t appears beyond doubt that the plaintiff[s] can prove no set of facts in support of [their] claim which would entitle [them] to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957). The district court therefore did not abuse its discretion in denying the plaintiffs' request for leave to amend.

CONCLUSION

For the foregoing reasons, the judgment of the district court is affirmed.

APPENDIX B — MEMORANDUM OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK FILED MAY 14, 2003

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

MDL. No. 1408 (ILG)

IN RE TAMOXIFEN CITRATE ANTITRUST LITIGATION

MEMORANDUM
MDL No. 1408 (ILG)

GLASSER, District Judge:

SUMMARY

Plaintiffs are eighteen individuals (the "consumer plaintiffs"), eleven organizations (or their trustees) which provide certain medical benefits for their members (the "third-party payor plaintiffs"), and six consumer advocacy groups representing consumer plaintiffs (the "consumer advocacy plaintiffs") (collectively, "Plaintiffs"). Plaintiffs bring this action essentially alleging that defendant Zeneca, Inc. (together with co-defendant Astrazeneca Pharmaceuticals LP, "Zeneca") entered into an agreement with defendant Barr Laboratories, Inc. ("Barr") (collectively, "Defendants") that, while nominally settling an appeal of a judgment that declared the patent for the drug tamoxifen citrate ("tamoxifen") invalid, in fact monopolized and allocated the United States market for tamoxifen. Plaintiffs allege that this agreement violated the laws of the United States and the laws of twenty-

two states. Defendants now move to dismiss the complaint on a variety of grounds. For the reasons states below, their motions are granted.

BACKGROUND

The actions involve the drug tamoxifen, the most essential drug for treatment of breast cancer.[1] Breast cancer is the most common malignancy and is one of the leading causes of death among women. During the 1990's, more than 1.5 million women in the United States were newly diagnosed with breast cancer. Tamoxifen is a synthetic hormone developed in the 1970's that is used, in addition to or in lieu of more drastic forms of therapy, to treat both early and advanced-stage breast cancer and to prevent recurrence. Tamoxifen has become the most widely prescribed treatment for breast cancer, and indeed is the single most-prescribed drug in the world for any cancer. The World Health Organization lists tamoxifen as an "Essential Drug," and tamoxifen is the standard of comparison in most clinical trials.

On August 20, 1985, Imperial Chemical Industries, PLC ("ICI") obtained United States Patent 4,536,516 (the '516 Patent) for tamoxifen. In December 1985 Barr filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA"), requesting approval to sell a generic bioequivalent version of the pioneer drug tamoxifen. An ANDA filing is governed by the Hatch-

1. Unless otherwise noted, the facts in this background are drawn from the Corrected Consolidated Class Action Complaint (the "Complaint") filed by Plaintiffs.

Appendix B

Waxman Act, 21 U.S.C. § 355, which provides an expedient method of obtaining FDA approval to bring generic bioequivalent drugs to the market. In addition to affirming that the generic drug contains the same active ingredient(s) as the patented drug already approved and listed by the FDA, an ANDA filer must certify why the patent would not be infringed pursuant to one of four reason:

I. No patent was in fact filed for the pioneer drug;

II. The patent for the pioneer drug has expired;

III. The patent for the pioneer drug will expire on a particular date *and* the ANDA filer will not market its generic product before that date; or

IV. The patent for the pioneer drug is invalid or will not be infringed upon the proposed generic product.

See 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

Upon the filing of an ANDA with a paragraph IV certification, the holder of the patent whose validity is being questioned may bring an action for declaratory judgment against the ANDA filer. Such a lawsuit has the effect of staying FDA consideration and approval of the ANDA for thirty months or until the date of a court decision as to the validity of the patent, whichever comes first. *See* 21 U.S.C. § 355(j)(5)(B)(iii). A court, in its discretion, however, may

extend the stay if the litigation is not resolved within the thirty month period. *See id.* One of the benefits of being the first ANDA filer to obtain FDA approval is an exclusive 180-day period in which to sell the generic drug free from other generic drug competition. *See* 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day period of market exclusivity is triggered either by the first sale of the applicant's product or when a court determines either that the patent is invalid or will not be infringed, whichever is earlier.[2] *Id.*

Barr's ANDA application, as amended in September 1987, certified that the '516 Patent was invalid and unenforceable. Within forty-five days of receiving notice of Barr's ANDA application, ICI sued Barr for patent infringement in the Southern District of New York.[3] ICI's patent infringement suit against Barr was tried before the late Honorable Vincent L. Broderick. On April 20, 1992, Judge Broderick held that the '516 Patent was invalid and unenforceable because ICI wrongfully withheld relevant

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2. At the time of Barr's ANDA, the court determination trigger was interpreted to be a final, non-appealable decision by a court. In light of two subsequent district court decisions, the FDA amended its regulation defining "court action" so that a district court determination of patent invalidity is now considered to be a final decision triggering the 180-day exclusivity period. *See* 21 C.F.R. § 314.107(c) (interim rule).

3. ICI's lawsuit also named as a defendant Heumann Pharma GmbH & Company ("Heumann"), Barr's supplier of tamoxifen. Heumann was subsequently dismissed from the suit in accordance with the terms of a stipulation of settlement. According to the Complaint, Heumann agreed to be bound by any determination of the validity of the '516 Patent.

material from the United States Patent and Trademark Office. *Imperial Chem. Industries, PLC v. Barr Labs., Inc.*, 795 F.Supp. 619 (S.D.N.Y.1992) (" *ICI v. Barr* "). ICI appealed that determination to the Federal Circuit.

Zeneca and Barr Settle the Patent Infringement Dispute

In 1993, while the appeal was pending, Zeneca (which had recently succeeded to ICI's rights in the '516 Patent) and Barr entered into a settlement agreement (the "Settlement Agreement"). Pursuant to the Settlement Agreement, Barr withdrew its challenge to the validity of the '516 Patent and amended its ANDA application to certify that it would not seek to market its generic version of tamoxifen until the patent expired. In return, Zeneca paid Barr $21 million and licensed Barr to sell tamoxifen manufactured by Zeneca in the United States, including Puerto Rico and the District of Columbia. The Settlement Agreement was conditioned upon the Federal Circuit vacating Judge Broderick's judgement declaring the '516 Patent invalid.[4]

Plaintiffs allege that, as part of the Settlement Agreement, Barr and Zeneca also agreed that Barr would not commercially market its generic product to avoid triggering the 180-day exclusivity period. Zeneca and Barr's understanding allegedly was that, although Barr's ANDA application would be amended to paragraph III, if a subsequent ANDA filer successfully invalidated the '516

4. Zeneca also promised to pay Heumann a sum of cash equal to $9.5 million at the time of settlement and $35.9 million over a ten year period in exchange for Heumann's promise to discharge all claims related to the '516 Patent.

Patent then Barr would insist upon its exclusivity rights (as the first paragraph IV filer) and not commercially market the generic until 2002, thereby delaying the triggering of the 180-day exclusivity period.

Barr and Zeneca filed a Joint Motion to Dismiss the Appeal as Moot and to Vacate the Judgment Below. No copy of the Settlement Agreement was presented to the Court of Appeals. Sidmak Laboratories, Inc. ("Sidmak"), a generic drug manufacturer, sought leave to file, untimely, a brief as amicus curiae objecting to dismissal of the appeal. On March 19, 1993, the Federal Circuit granted the joint motion pursuant to its practice at the time to honor settlement agreements and denied Sidmak's motion. *See Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811 (table) (Fed.Cir.1993).[5] On March 23, 1993 Judge Broderick vacated the judgement and dismissed the case. Consequently, the '516 Patent remained valid, and Zeneca's Nolvadex® brand and Barr's licensed version of tamoxifen were the only products on the market. Although Barr could produce tamoxifen at a lower cost than the price at which it obtains tamoxifen from Zeneca under license, Barr's ability

5. Since that time, the Supreme Court has ruled that federal appellate courts may not direct the *vacatur* of a district court order based solely on a settlement agreement between the parties. *See United States Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18, 27, 115 S.Ct. 386, 130 L.Ed.2d 233 (1994). However, the Federal Circuit subsequently held that *United States Bancorp* applied only to cases still pending when *United States Bancorp* was decided, and thus the *vacatur* (issued prior to *United States Bancorp*) was proper. *See Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144 (Table), 1997 WL 168318, at *2 (Fed.Cir.1997).

to price the licensed version is restrained by that higher cost.

Subsequent ANDAs for Tamoxifen

In June 1994, Novopharm Ltd. ("Novopharm") filed an ANDA for tamoxifen that claimed the '516 Patent was invalid.[6] Subsequently, on January 18, 1995 Zeneca sued Novopharm for patent infringement. Before discovery began, Novopharm moved for summary judgment on the basis that the *ICI v. Barr* Judgment should be given preclusive effect and that the *vacatur* should be ignored. (Change Dec., Ex. 8.) The district court disagreed. *Zeneca Ltd. v. Novopharm Ltd.*, 923 F.Supp. 74 (D.Md.1995). After discovery was completed, Novopharm again moved for summary judgment, this time arguing that the court should adopt two factual findings made in the vacated judgment in *ICI v. Barr* under the doctrine of issue preclusion. *Zeneca Ltd. v. Novopharm Ltd.*, 919 F.Supp. 193, 196 (D.Md.1996). Again the district court denied the motion, *id.* at 196-98, and subsequently found that Zeneca did not engage in inequitable conduct before the PTO, and therefore granted judgment to Zeneca upholding the validity of the '516 Patent. (Chang Dec., Exs. 9 and 10.) On appeal, the Federal Circuit affirmed the validity of the '516 Patent in an unpublished decision. *Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144, 1997 WL 168318 (Fed.Cir.1997) (Table).

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6. The facts about the Novopharm ANDA and subsequent litigation are not in the Complaint, but are based on court decisions publicly available on Westlaw and papers submitted to those courts. (*See* Chang Dec., Exs. 8-11).

Appendix B

In August 1994, Pharmachemie, B.V. ("Pharmachemie") submitted an ANDA with a paragraph III certification for its version of tamoxifen. In February 1996, Pharmachemie amended its ANDA to include a paragraph IV certification. Zeneca then sued Pharmachemie for patent infringement within 45 days of the amendment, *see Zeneca Ltd. v. Pharmachemie, B.V.*, Civ. 37 F.Supp.2d 85 (D.Mass.1999), triggering the statutory 30-month stay. The FDA gave tentative approval to Pharmachemie's ANDA on April 3, 1997. Before the 30-month stay expired, Zeneca moved the court to extend the stay. The motion was denied in a published decision. *Zeneca Ltd. v. Pharmachemie, B.V.*, 16 F.Supp.2d 112 (D.Mass.1998). Although not mentioned in the Complaint, prior to trial the district court granted Zeneca's motion for partial summary judgment on the issues of collateral estoppel, patent misuse, and unclean hands. *Zeneca Ltd. v. Pharmachemie, B.V.*, 37 F.Supp.2d 85 (D.Mass.1999). At trial, Pharmachemie argued that the '516 Patent was unenforceable because Zeneca had engaged in inequitable conduct before the PTO and that the patent was invalid because it did not set forth the "best mode" for carrying out the invention, as required by 35 U.S.C. § 112. *Zeneca Ltd. v. Pharmachemie, B.V.*, Civ. No. 96-21413(RCL), slip op. at 3 (D.Mass. Sept. 14, 2000). The court granted judgment as a matter of law to Zeneca on the inequitable conduct claim, and a jury returned a verdict in Zeneca's favor on the best mode claim. *Id.* at 4-5. No appeal was taken.

In January 1996, Mylan Pharmaceuticals, Inc. ("Mylan") submitted an ANDA with a paragraph IV certification for its version of tamoxifen. Zeneca sued Mylan in the Western District of Pennsylvania for patent infringement within

45 days of that certification, also thus triggering the 30-month statutory stay of FDA approval for Mylan's ANDA. Mylan then agreed to follow the *Pharmachemie* court's decision, and the case was dismissed after that court ruled in favor of Zeneca. *Zeneca Ltd. v. Mylan Labs.*, No. 96-333 (W.D.Pa. Nov. 30, 2000).

Barr's Petition to the FDA

While Mylan and Pharmachemie's actions were pending before the district courts, on June 26, 1998, Barr filed a Petition for Stay of Action with the FDA to block final marketing approval for Mylan's ANDA (the "FDA Petition"). Although Barr had amended its ANDA from a paragraph IV certification to a paragraph III certification after the *ICI v. Barr* settlement, Barr contended in its FDA Petition that it was entitled nonetheless to the 180-day exclusivity period as the first paragraph IV filer. The FDA acceded to Barr's petition and announced in a letter to Barr, dated March 2, 1999, that it would stay any approval of tamoxifen ANDAs until 180 days after the date of the first commercial marketing of the drug under Barr's ANDA or the date of a final court decision holding the tamoxifen patent to be invalid or not infringed.

Pharmachemie and Mylan later successfully challenged this decision in court. *Mylan Pharmaceuticals, Inc. v. Henney*, 94 F.Supp.2d 36, 54 (D.D.C.2000), *vacated as moot sub nom. Pharmachemie, B.V. v. Barr Labs., Inc.*, 276 F.3d 627 (D.C.Cir.2002). In response to the district court's order, on June 26, 2000 the FDA revoked Barr's eligibility for the 180-day exclusivity period.

Appendix B

Allegations Regarding Injury

Plaintiffs essentially allege that but for the Settlement Agreement, the judgment declaring the '516 Patent invalid would have been affirmed, Barr's 180-day exclusivity period would have been triggered, and a competitive market for tamoxifen would have resulted. Plaintiffs further allege that Zeneca and Barr maintain a duopoly in which Zeneca illegally shares its monopolistic profits with Barr through the licensing agreement. The discount for purchasing tamoxifen distributed by Barr is only about 5% compared to the price for Zeneca's brand name version, Nolvadex®. Plaintiffs allege that because the Settlement Agreement permits Zeneca and Barr to charge artificially inflated prices, Plaintiffs were overcharged for tamoxifen.

Procedural History

The Settlement Agreement has spawned thirty lawsuits around the country, all of which have been transferred to this Court, pursuant to 28 U.S.C. § 1407, by the Judicial Panel on Multi-District Litigation for coordination of pre-trial matters. A coordinated class action complaint was subsequently filed. The complaint alleges that the Settlement Agreement enabled Zeneca and Barr to (I) resuscitate a patent that Barr had established by clear and convincing evidence was invalid and unenforceable; (ii) confine the entire United States market for tamoxifen to one manufacturer, Zeneca; (iii) share the monopoly profits of Zeneca's tamoxifen; (iv) avoid price competition and maintain artificially inflated market prices for Nolvadex® and its Zeneca-manufactured generic licensed to Barr; and (v) exclude competition from

other generic manufacturers. (*See* Compl. ¶ 53.) The Complaint further alleges that but for the Settlement Agreement, Judge Broderick's judgment would have been affirmed, the FDA would have granted final approval to Barr's generic version of tamoxifen, Barr would have marketed a generic version of tamoxifen, a highly competitive market for tamoxifen would have developed after Barr's 180-day exclusivity period had run, and Zeneca would have been collaterally estopped from enforcing the '516 Patent against other ANDA filers. (*See id.* ¶ 54.) Plaintiffs also allege that by refusing to market a generic version of tamoxifen, Barr could prevent another challenger to the '516 Patent from being able to market the generic counterpart.

STANDARD FOR MOTION TO DISMISS

When deciding a motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6), the court must take all allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957); *Niagara Mohawk Power Corp. v. Federal Energy Reg. Comm'n*, 306 F.3d 1264, 1267 (2d Cir.2002). A complaint should not be dismissed "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *FD Property Holding, Inc. v. U.S. Traffic Corp.*, 206 F.Supp.2d 362, 369 (E.D.N.Y.2002) (internal quotation marks omitted). However, the Court may consider matters of public record, such as court decisions, statutes, and documents such as briefs filed with courts and other public bodies. *See, e.g., Papasan v. Allain*, 478 U.S. 265, 268, 106 S.Ct. 2932, 92 L.Ed.2d 209 n. 1 (1986) ("Although this case comes to us on

a motion to dismiss under Federal Rule of Civil Procedure 12(b), we are not precluded in our review of the complaint from taking notice of items in the public record . . . ."); *Rothman v. Gregor,* 220 F.3d 81, 92 (2d Cir.2000).

DISCUSSION

I. Whether the Settlement Agreement Violated the Sherman Act

A. General Principles

Section 1 of the Sherman Act provides: "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal . . . ." 15 U.S.C. § 1.

As a general rule, an agreement between a monopolist and a potential competitor to divide the market between them and exclude other competition is per se illegal under Section 1. *See United States v. Topco Assoc., Inc.,* 405 U.S. 596, 608, 92 S.Ct. 1126, 31 L.Ed.2d 515 (1972) ("One of the classic examples of a per se violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition.").

However, the holder of a patent legally maintains a monopoly over his or her product and may "prevent other[s] from utilizing his discovery without his consent." *Zenith Radio Corp. v. Hazeltine Research, Inc.,* 395 U.S. 100, 135, 89 S.Ct. 1562, 23 L.Ed.2d 129 (1969). A patent holder also

"may assign to another his patent, in whole or in part, and may license others to practice his invention." *Id.* "Simply stated, a patent holder is permitted to maintain his patent monopoly through conduct permissible under the patent laws." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir.1981).

This permissible conduct includes the settlement of patent litigation by a licensing agreement. *See Standard Oil Co. v. United States,* 283 U.S. 163, 170, 51 S.Ct. 421, 75 L.Ed. 926 (1931) ("Where there are legitimately competing claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act."); *Duplan Corp. v. Deering Milliken, Inc.*, 540 F.2d 1215, 1220 (4th Cir.1976) ("the settlement of patent litigation, in and of itself, does not violate the antitrust laws"); *Scientific Corp. v. Schneider (Europe) AG,* 983 F.Supp. 245, 269 (D.Mass.1997) ("It is well established that settlement of patent litigation through a cross-licensing agreement does not in and of itself violate the antitrust laws."), *appeal dism'd,* 152 F.3d 947 (Fed.Cir.1998) (Table).

B. Bad Faith Patent Settlements Can Violate the Antitrust Laws

A patentee, however, cannot go "beyond the limits of the patent monopoly." *United States v. Line Material Co.*, 333 U.S. 287, 308, 68 S.Ct. 550, 92 L.Ed. 701 (1948). As the Supreme Court held in *Standard Oil,* the very case that established that patent settlements do not alone violate the antitrust laws: " *Any* agreement between competitors may

be illegal if part of a large plan to control interstate markets." 283 U.S. at 169, 51 S.Ct. 421 (emphasis added).

For example, in *United States v. Singer Co.*, 374 U.S. 174, 83 S.Ct. 1773, 10 L.Ed.2d 823 (1963), Singer and a Swiss company Gegauf (along with a third Italian company) settled threatened and actual interference proceedings before the United States Patent Office (the precursor to the modern PTO) by, *inter alia*, cross-licensing patents regarding sewing machines to one another. Thereafter, Gegauf assigned its patent application to Singer which then received the patent. Evidence showed that Singer and Gegauf also sought the power to better enforce these patents against Japanese competitors who might seek to import sewing machines into the United States that infringed upon Gegauf's patents. *Id.* at 191, 195 n. 9, 83 S.Ct. 1773. Singer undertook steps to exclude the Japanese competition by bringing a proceeding before the United States Tariff Commission (which only an American company like Singer could do) to exclude all foreign machines that fell within *Gegauf's* patent from entering the United States. *Id.* at 194, 195-96. Although the District Court found that no illegal conspiracy existed because the primary purpose of the agreements was to settle the patent disputes, the Supreme Court reversed and found that Singer had gone beyond protecting its own patents and instead had combined with Gegauf against other competitors. *Id.* at 194, 83 S.Ct. 1773. In his concurring opinion, Justice White was most troubled by the possibility that by not pursuing the interference claims, Singer and Gegauf collusively deprived the Patent Office of notice of prior art that would sap the proposed patent of the novelty that justifies

a patent monopoly in the first place. *Id.* at 199-200, 83 S.Ct. 1773 (White, J., concurring).

As explained by the Fourth Circuit,

> It is only when settlement agreements are entered into in bad faith and are utilized as part of a scheme to restrain or monopolize trade that antitrust violations occur . . . . *Singer* makes clear that it is not the mere act of settlement but the intent of the parties in entering into that settlement and their actions pursuant thereto that, in law constitute such a violation [of the Sherman Act].

Duplan Corp., 540 F.2d at 1221-22.[7] In other words, Plaintiffs can establish a Sherman Act violation by alleging facts from which it can be inferred that Zeneca and Barr entered into the Settlement Agreement in bad faith and used the agreement to restrain or monopolize trade.

C. Application of Antitrust Laws to Patentee-ANDA Applicant Settlements

In opposition to the motion to dismiss, Plaintiffs point out that at least three courts have reviewed allegedly bad faith settlements between patentees and ANDA filers and found that Sherman Act claims can be stated for reasons similar to those set forth in *Singer*. Plaintiffs argue that this

7. In *Duplan Corp.*, the court held that the illegality of such an agreement could not be presumed solely by the existence of a letter from a settling party's attorney opining that the party would prevail if it pursued the patent infringement case. 540 F.2d at 1221.

case is comparable to these other cases, and that their allegations accordingly state a claim under the Sherman Act. Because each case arises under its own complex set of facts, those facts are set forth here in some detail.

1. Terazosin Hydrochloride

Abbott Laboratories registered patents regarding the drug terazosin hydrochloride ("terazosin") and received approval to market it for the treatment of hypertension and enlarged prostate. *See In re Terazosin Hydrochloride Antitrust Litig.*, 164 F.Supp.2d 1340, 1343 (S.D.Fla.2000), *pet. appeal granted*, No. 02-101-71-J (11th Cir. Apr. 19, 2002). Subsequently two generic manufacturers, Zenith Goldline Pharmaceuticals, Inc. and Geneva Laboratories, filed ANDAs with paragraph IV certifications challenging the validity of Abbott's patents and began racing toward first approval from the FDA. *Id.* at 1343-44. By late March 1998, although Abbott was engaged in infringement litigation with both challengers, the 30-months stays were expiring and both Zenith and Geneva were posed to being marketing generic versions of terazosin. *Id.* at 1345-46.[8]

However, Abbott settled its litigation with Zenith by paying $3 million up front, and $6 million per quarter on condition that Zenith did "not sell, offer for sale, donate or

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8. With regard to Zenith, on October 1, 1997, Zenith's motion for preliminary injunctive relief was denied. *Terazosin*, 164 F.Supp.2d at 1345. Zenith's appeal of that order was pending before the Federal Circuit when the parties settled. *Id.* at 1346. With regard to Geneva, patent infringement litigation was proceeding apace in the Northern District of Illinois.

otherwise commercially distribute in the United States" terazosin, and upon Zenith's promise not to assist any other company to gain FDA approval to market terazosin. *Id.* at 1346. With regard to Geneva, Abbott agreed to pay $4.5 million per month to Geneva to refrain from marketing any generic terazosin until any other generic began selling or until Geneva received a final, unappealable judgment that its generic terazosin did no infringe Abbott's patents. *Id.* However, Geneva and Abbott would continue to litigate the issue, but Geneva would support Abbott in extending the 30-month stay and promised "to use its best efforts to oppose any attempt by any ANDA applicant" to market generic terazosin prior to the date provided for in then-existing FDA regulations. *Id.* at 1347 n. 7. In other words, *Terazosin* involved two simultaneous horizontal agreements-one permanently ending possible competition from Zenith, and another buying time and cooperation from Geneva.

In an antitrust action, the district court found that by these agreements "Geneva and Zenith foreswore competing with Abbott in the United States market for terazosin hydrochloride drugs and promised to take steps to forestall others from entering the markets in exchange for millions of dollars . . . ." *Id.* at 1348-49. The court held that such agreements were blatantly anti-competitive by dividing the market among competitors (a horizontal restraint) and that such agreements were illegal *per se. Id.*

2. Cardizem CD

Marion Merrell Dow ("Dow") introduced in 1982 a new pioneer drug (diltiazem hydrochloride) for treating

hypertension and angina that was patented and marketed in a once-daily, immediate-release delivery method under the name Cardizem. *In re Cardizem CD Antitrust Litig.*, 105 F.Supp.2d 618, 629 (E.D.Mich.2000) ("*Caridzem I*"). Eventually, the product was improved by releasing it in a once-daily "sustained release" delivery method produced under license from a separate patent holder ("Elan"), and rebranded as Cardizem CD. *Id.* In 1992, Biovail International Corporation began developing its own once-daily generic of Cardizem, and began working with Hoechst-Roussel Pharmaceuticals ("HRP") to develop a sustained release delivery method of its own to be called Tiazac. *Id.* Upon HRP's filing an ANDA stating that Tiazac did not infringe on Cardizem's patents, Dow sued for patent infringement on November 11, 1993.

In late 1994, HRP's parent Hoechst AG agreed to acquire Dow, and HRP ended its partnership with Biovail. *Id.* at 630. Biovail in turn sued Hoechst for breach of contract and antitrust violations, and the parties reached a master settlement of both litigations in 1995 in which they agreed not to challenge each others' respective products. *Id.* After an FTC investigation into the Hoechst-Dow merger, Hoechst agreed to support Biovail's applications to the FDA for approval of Tiazac by directing the FDA to reference Biovail's applications with its own studies used for Cardizem. *Id.* The only remaining barrier to Tiazac's entry to the market was an outstanding patent dispute between Biovail and Elan over the delivery method. *Id.* When Hoechst discovered that the Biovail-Elan litigation would be settled, however, and that Biovail intended to file a New Drug Application (rather than an ANDA) to avoid the 180-day exclusivity period to

which another generic manufacturer (Andrx) already had claim, Hoechst refused to permit Biovail to reference the studies. *Id.* Accordingly, without clinical studies that Biovail could reference, the FDA refused to license Tiazac. *Id.* at 631.

Meanwhile, in September 1995 Andrx had filed its ANDA certifying that Cardizem would not be infringed, and Hoechst sued for patent infringement in January 1996 thereby triggering the 30-month stay. *Id.* On September 17, 1997, the FDA preliminarily approved Andrx's generic version of Cardizem CD, which meant that Andrx could have begun marketing the product as early as July 4, 1998. *Id.* at 632. Shortly thereafter, Hoechst and Andrx entered into an agreement, by the terms of which Andrx would refrain from marketing its generic version of Cardizem CD until all appeals in the litigation were concluded and would receive quarterly payments of $10 million from Hoechst beginning on July 9, 1998. *Id.*

By August 20, 1998, consumer plaintiffs began filing lawsuits alleging violations of indirect purchaser state laws. *Id.* On June 9, 1999, Hoechst settled its patent litigation with Andrx by paying Andrx an additional $50 million. *Id.* The district court held that the agreement was a naked restraint on trade subject to *per se* analysis, and granted plaintiffs partial summary judgment. *See In re Cardizem Antitrust Litig.*, 105 F.Supp.2d 682, 699-705 (E.D.Mich.2000) ("*Cardizem II* "), *appeal filed,* No. 00-2483 (6th Cir. Dec. 19, 2000).

3. Procardia XL

Pfizer, Inc. ("Pfizer") filed a New Drug Application for extended release nifedipine, a hypertension treatment, which Pfizer markets in three strengths (30, 60 and 90 mg) under the brand name Procardia XL. *See Biovail, Inc. v. Mylan Labs, Inc., et al.*, Civ. No. 1:01CV66, slip op. at 5 (N.D.W.Va. Mar. 22, 2002). In April 1997, Mylan filed an ANDA for 30 mg nifedipine with the FDA. *Id.* Pfizer sued Mylan for patent infringement, and the case settled in March 2000, under terms by which Mylan received a license for a "private label" version of Procardia, and Mylan would not market its generic version covered by its ANDA. *Id.*, slip op. at 5-6.

Biovail filed its ANDA for 30 mg and 60 mg nifedipine after Mylan's filing, but was unable to market either version until one of its licensees forced the FDA's hand by petitioning for final approval, which the FDA granted on February 6, 2001. *Id.*, slip op. at 6. The FDA ruled that Mylan had effectively converted its paragraph IV certification to a paragraph III certification upon settling with Pfizer, and that marketing the "private label" version triggered the 180-day exclusivity period. *Id.*, slip op. at 6-7.

Biovail then sued Mylan and Pfizer for unreasonably restraining trade by agreeing to reduce competition and hindering Biovail's entry into the market for four months. Biovail claimed that because buyers in the market for Procardia XL prefer to obtain different dosage strengths from the same supplier, the restrictions on 30 mg Procardia XL prevented Biovail from marketing effectively its 60mg version. *Id.* The district court found that these allegations

were sufficient to state a claim that Mylan and Pfizer conspired to produce anti-competitive effects. *Id.*, slip op. at 11.

D. Analysis

Defendants claim that the Settlement Agreement at issue here is unlike the agreements found suspect in other cases, and that it is a defensible resolution of patent litigation and not a restraint of trade. Further, Defendants argue that further inquiry into the vacated decision "would effectively strip settlements of value and finality by permitting collateral suits by third parties who were allegedly deprived of a 'favorable' decision." (Def. Consolidated Reply Mem. at 7.)

1. Plaintiff's Claims Are Not an Impermissible Collateral Attack on the *Vacatur* Order

Defendants argue that *vacatur* was an appropriate course for the Federal Circuit to take given precedent current at the time. (Def. Consolidated Mem. at 27-30), a point which Plaintiffs do not contest. (Pl. Opp. Mem. at 45.) Defendants further argue that Plaintiffs' claims are fundamentally inconsistent with the *vacatur*; comparing this to a collateral attack on a judgment. However, there is a difference. As noted by Defendants, with *vacatur* potential future litigants (such as Plaintiffs) are no worse off because "the only damage to the public interest is that the validity of [the intellectual property rights] *would be left to future litigation.*" *Major League Baseball Properties, Inc. v. Pacific Trading Cards, Inc.*, 150 F.3d 149, 152 (2d Cir.1998) (settlement of trademark dispute) (emphasis added).

Plaintiffs are not trying to deprive the settlement of its value to either party, since both parties have apparently received the benefit of the bargain-Zeneca was able to eliminate a significant challenge to the validity of its '516 Patent, and Barr was well compensated. If Plaintiffs can allege facts that the Settlement Agreement was executed in bad faith, they will have stated a claim that the Settlement Agreement was an illegal restraint of trade. Accordingly, this Court will examine whether the allegations in the Complaint state claims as a matter of law.

2. The Zeneca-Barr Settlement Agreement is Different from Other Patentee-ANDA Agreements

Defendants claim that even if settlements between patentees and ANDA filers are not immunized from antitrust scrutiny, the Settlement Agreement between Zeneca and Barr is significantly different from those found in other cases to violate the Sherman Act. Defendants are correct.

a. The Settlement Agreement Terminated the Entire Litigation

One crucial difference is that the Settlement Agreement in fact ended the litigation outright. Barr and Zeneca actually resolved their complex litigation, and in so doing they cleared the field for other generic manufacturers to challenge the patent. Indeed, at least three other generic manufacturers accepted the challenge, filed ANDAs with paragraph IV certifications, and in each case, Zeneca successfully litigated the validity of the '516 patent.

In comparison, in *Cardizem,* Hoechst paid Andrx to refrain from marketing its generic after the 30 months stay expired, but did not otherwise end the litigation. 105 F.Supp.2d at 632. Similarly, in *Terazosin,* the patentee settled outright one case (the Zenith Agreement), but took advantage of the existence of a second case to prolong the 30 month stay. 164 F.Supp.2d at 1346-47. Of course, these sorts of agreements sap a generic filer's motivation to finish the litigation, and therefore produce a perverse result under the Hatch-Waxman Act by providing an incentive to delay the patent litigation without "clearing the way" for other ANDA filers. In the end, these agreements meant that the litigation could drag on without providing other generic manufacturers (even those who were not sued for patent infringement like Biovail) a means by which to enter the market.

The same cannot be said about the present agreement. The conclusion of the litigation meant that other ANDA filers were free to litigate the validity of the '516 patent. Instead of leaving in place an additional barrier to subsequent ANDA filers, the Settlement Agreement in fact removed one possible barrier to final FDA approval-namely, the existence of ongoing litigation between an existing ANDA filer and a subsequent filer.

b. Barr's FDA Petition Five Years After the Settlement Agreement Cannot Serve as a Basis for Liability

Plaintiffs contend that Defendants' argument regarding "clearing the field" for other ANDA filers is belied by Barr's FDA Petition (allegedly pursuant to the Settlement

Agreement) that sought to preserve Barr's 180-day exclusivity period. Barr's FDA Petition was premised on an interpretation of FDA regulations that only Barr's own marketing of a generic version of tamoxifen or a final court decision could trigger the 180-day period. Given the existence of two pending infringement suits, Barr's FDA Petition sought to assert that its previous ANDA was superior in determining who might receive the 180-day exclusivity period.[9]

Two of the bases for the FDA Petition came only years after the Settlement Agreement. First, until 1997, FDA regulations interpreting the 180-day exclusivity period made it clear that the ANDA filer which first successfully defended against the patent infringement suit would receive the 180-day exclusivity period. The relevant language of the Hatch-Waxman Act provides, however, that a subsequent ANDA paragraph IV application "shall be made effective not earlier than one hundred and eighty days after-(I) the date [the] Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to

9. It must be noted that Barr did *not* seek similar relief when Novopharm filed its ANDA and challenged the '516 patent between 1994 and 1997. Only after the events in 1997 and 1998 described above in the text did Barr attempt to assert its rights. If Barr intended to protect its exclusivity period on behalf of itself and Zeneca *pursuant to the Settlement Agreement,* Barr's inactivity during the pendency of the Novopharm litigation is inexplicable.

be invalid or not infringed, whichever is earlier." 21 U.S.C. 355(j)(5)(B)(iv).

In light of the actual language of the Hatch-Waxman Act, in 1997 a district court invalidated the FDA's "successful defense" regulation on the grounds that it contradicted the unambiguous language of the Hatch-Waxman Act. *See Mova Pharmaceutical Corp. v. Shalala,* 955 F.Supp. 128 (D.D.C.1997) (enjoining FDA from giving final approval to second ANDA filer who successfully defended against patent infringement suit). The Court of Appeals for the District of Columbia Circuit upheld this decision on the grounds that the successful defense regulation was inconsistent with the statutory language and that the plain meaning of the statutory language would not produce an absurd result. *See Mova Pharmaceutical Corp. v. Shalala,* 140 F.3d 1060, 1070-73 (D.C.Cir.1998).

In other words, until 1997, if Novopharm, Pharmachemie or Mylan had successfully defended against Zeneca's patent infringement suit, the first one to do so would receive the 180-day exclusivity period pursuant to then-existing FDA regulations. After the *Mova Pharmaceutical* decisions in 1997 and 1998, Barr's claim to the 180-day exclusivity period was strengthened significantly (if not wholly created) since the FDA could not permit the applications of the other generic manufacturers to take effect until 180 days elapsed after such a court decision.

Second, the FDA specifically argued in the *Mova Pharmaceutical* appeal that its regulations requiring that an ANDA filer who loses the patent infringement suit be treated

as a paragraph III filer was "housekeeping" and not intended to affect the application of the 180-day exclusivity period. *Id.*, 140 F.3d at 1070. Although the D.C. Circuit confessed some disbelief at this interpretation, it was willing to defer to the FDA's interpretation regarding an issue not directly before the court. *Id.* at 1070 n. 13 ("We confess to not understanding how the FDA can reconcile its reading with the language of its own regulation, but stress that this issue has not been briefed and is not necessary to the decision in this case.")[10]

Two months after the D.C. Circuit's decision in *Mova Pharmaceutical,* Barr filed its FDA Petition. Barr argued that the Hatch-Waxman Act, as interpreted by the D.C. Circuit, required that the FDA stay approval of Mylan's ANDA application since the FDA regulation requiring a "successful defense" were no longer valid. Barr also used the FDA's own arguments before the D.C. Circuit to support its position that, notwithstanding the paragraph III amendment Barr filed after the Settlement Agreement, it should be entitled to the 180-day exclusivity period whenever and by whomever the period was triggered.

Barr's FDA Petition was thus an attempt to petition a governmental body in order to protect an arguable interest in a statutory right based on recent developments in the court

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10. The district court that reviewed the FDA's decision to grant Barr's FDA Petition criticized and rejected this confusing interpretation of the interplay between paragraph III and paragraph IV certification. *See Mylan Pharm. v. Henney,* 94 F.Supp.2d 36, 57 (D.D.C.2000), *vacated as moot sub nom., Pharmachemie B.V. v. Barr Labs., Inc.,* 276 F.3d 627 (D.C.Cir.2002).

and at the FDA. As such, the FDA Petition was protected activity under the First Amendment, and long-settled law established that the Sherman Act, with limited exceptions, does not apply to petitioning administrative agencies.[11] *See Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961) (Sherman Act does not apply to joint lobbying of state legislature); *United Mine Workers of America v. Pennington*, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965) (extending *Noerr* to joint activity to persuade administrative agency). Of course, as described below, plaintiffs are also unable to allege any anti-competitive impact from Barr's FDA Petition, both because the FDA's decision in Barr's favor

11. Plaintiffs admit they cannot and do not seek to argue that Barr's FDA Petition falls within the sham exception to the *Noerr-Pennington* doctrine. (Pl. Opp. Mem. at 52-53.)

Given the disposition of these motions, this Court need not address the more difficult question of whether the Settlement Agreement itself is protected by the *Noerr-Pennington* doctrine. *Compare Hise v. Philip Morris, Inc.*, 46 F.Supp.2d 1201, 1206 (N.D.Okla.1999), *aff'd*, 208 F.3d 226, 2000 WL 192892 (10th Cir.2000) (holding that concerted activities *among co-defendants* in jointly negotiating Master Settlement Agreement with 46 states and 6 other jurisdictions was protected activity) *with Cardizem*, 105 F.Supp.2d at 641 (collecting and agreeing with cases that hold settlements *between adverse parties* are not protected); *see* Raymond Ku, *Antitrust Immunity, the First Amendment, and Settlements: Defining the Boundaries of the Right to Petition*, 33 Ind. L.Rev. 385, 429 (2000) (arguing that *Noerr-Pennington* would not apply because "when asked to approve a settlement agreement, a court is not being asked to determine liability or approve the substance of the agreement.").

was overturned, *see Mylan Pharm. v. Henney,* 94 F.Supp.2d 36, 57 (D.D.C.2000), *vacated as moot sub nom., Pharmachemie B.V. v. Barr Labs., Inc.,* 276 F.3d 627 (D.C.Cir.2002), and because no generic manufacturer in fact ever received approval to enter the market.

c. The Allegations Lack the Continuing Behavior Found in Other Cases

The present case is also different in that no pattern of settlements or continuing behavior is involved. For example, in *Singer,* doubts arose over Singer's petition to the Tariff Commission because of references to another company (Pfaff) in Gegauf's assignment of rights. Singer and Gegauf returned to the negotiating table to delete those references, a "maneuver . . . for the purpose, as the trial court found, of giving Singer a better chance of prevailing before the Tariff Commission in its efforts to exclude infringing machines." *Singer,* 374 U.S. at 196, 83 S.Ct. 1773. The Court found that the conspiracy was "clearly illustrated" by this type of continuing behavior of Singer and Gegauf. *Id.* at 195, 83 S.Ct. 1773.

No similar maneuvering or continued behavior is alleged here. Certainly, there are no allegations that Zeneca and Barr ever acted in concert after the 1993 Settlement Agreement, and only one allegation (the Barr FDA Petition) of any allegedly anti-competitive activity after the Settlement Agreement was executed. Indeed, the only pattern of behavior discerned from the Complaint appears to be a vigorous defense of the '516 patent. Zeneca challenged every ANDA filer, and defeated the claims of patent invalidity on the merits

on two occasions (not including Mylan's decision to tie its fate to Pharmachemie's). While there may conceptually be a case where bad faith can be alleged based on a single event, the allegations here do not state a claim for bad faith settlement.

II. Plaintiffs Have Not Suffered Antitrust Injury

Plaintiffs' Sherman Act claims also fail to adequately plead antitrust injury. In order to state a claim under the Sherman Act, a plaintiff must allege facts that in addition to causation show "antitrust injury, which is to say [1] injury of the type the antitrust laws were intended to prevent and [2] that flows from that which makes defendants' acts unlawful. The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977).

A. Plaintiffs Suffered No Injury From the Settlement Agreement Because No Manufacturer Ever Received Approval to Market Generic Tamoxifen

The injury here (higher prices for tamoxifen) resulted from the existence of the '516 patent and not the Settlement Agreement, and because the purported injury flowed from the result of a lawful patent monopoly, no antitrust injury can exist. For example, in *NYNEX v. Discon, Inc.*, 525 U.S. 128, 119 S.Ct. 493, 142 L.Ed.2d 510 (1998), the Supreme Court held that no injury flowed from a regional Bell

operating company's unilateral decision to refuse to deal with one company. *Id.* at 136-37, 119 S.Ct. 493. Similarly, no antitrust injury occurs when a patent holder sues for infringement unless the patent was fraudulently procured or the infringement action was a sham. *In re Independent Service Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed.Cir.2000). Nor can a defendant in a patent infringement suit claim antitrust injury based on the costs of defending against the infringement or related costs caused by losing the infringement suit. *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1558 (Fed.Cir.1997), *partially overruled on other grounds by, Cybor Corp. v. FAS Tech, Inc.*, 138 F.3d 1448 (Fed.Cir.1998) (en banc).

Plaintiffs contend that Defendants caused injury because the Settlement Agreement was structured to license tamoxifen to Barr only at supra-competitive prices. (Pl. Opp. Mem. at 35.) Plaintiffs thus argue that this case is similar to *Ciprofloxacin,* where the court found that the allegation that the patentee would have negotiated licenses with generic manufacturers at *competitive* prices sufficed to allege antitrust injury. 166 F.Supp.2d 740, 749 (E.D.N.Y.2001). Even liberally interpreting the Complaint to encompass such allegations (which it does not) and despite the language in *Ciprofloxacin,* Defendants are correct to the extent that Plaintiffs are alleging injury based on the possibility that Zeneca would license its patent at competitive prices. As the Federal Circuit has noted, "[t]here is no reported case in which a court ha[s] imposed antitrust liability for a unilateral refusal to sell or license a patent." *Independent Service Orgs.*, 203 F.3d at 1326 (internal quotations omitted). No antitrust

injury can flow from the prices at which Zeneca licensed tamoxifen to Barr.

Plaintiffs' injuries thus must flow from the anti-competitive nature of the Settlement Agreement. As described above, this would entail proof of injury not from the decision by Zeneca to settle the patent litigation, but from the exclusion of other competitors in the market. However, as Defendants note, no generic manufacturer ever obtained FDA approval to bring the drug to market since all three manufacturers who filed with paragraph IV certifications failed to prove in court that the patents were invalid.

Antitrust injury, however, must be caused by something other than the regulatory action limiting entry to the market. For example, no antitrust injury was found where a potential competitor to a local electrical utility in Pittsburgh merged with the existing utility before receiving permission to compete from the state regulatory agency. *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 267-68 (3d Cir.1998). Similarly, another court has found that no antitrust injury existed to support an antitrust counterclaim brought by a second ANDA filer since it would not be able to compete in the market until (1) the patent was declared invalid and (2) the 180-day exclusivity period expired for the first filer. *See Bristol-Myers Squibb v. Copley Pharm., Inc.*, 144 F.Supp.2d 21, 23 (D.Mass.2000).

In the present case, the lack of competition in the market was not caused by the deployment of Barr's exclusivity period, but rather by the inability of the generic companies to invalidate or design around the '516 Patent. Indeed, in

Bristol-Myers, supra, the possibility of antitrust injury was more proximate since the second ANDA filer would have been able to enter the market relatively soon after the first ANDA filer. Here, absent any allegations that Barr conspired with Zeneca somehow to hinder either Novopharm, Pharmachemie or Mylan from establishing the invalidity of the '516 patent, there is no basis for the claim that competition could have existed. In this respect, the present case is quite different from *Terazosin,* where Geneva had received approval to begin marketing a generic capsule of terazosin, or from Procardia XL case, where Biovail in fact received approval to market its generic version despite the allegedly anti-competitive efforts to delay its entry.

Plaintiffs do argue that Barr's FDA Petition delayed approval of Mylan's ANDA, and that therefore this action prevented Mylan from marketing its generic version of tamoxifen. (Pl. Opp. Mem. at 37.) Even assuming that the Complaint alleges that Mylan would have marketed its generic tamoxifen before receiving a court order in its favor,[12] given the actual judgment against it in favor of Zeneca, Mylan never could have entered the market without infringing upon the '516 Patent. Plaintiffs, in other words, allege injury based on the lack of competition that could have only existed by illegally infringing on the '516 Patent. The lack of

12. The Complaint merely alleges that *Barr* (in its FDA Petition) claimed that Mylan "likely will begin marketing a generic version upon receiving FDA approval." (Compl.¶ 66.) This is somewhat different from *Plaintiffs* claiming that Mylan would enter the market before actually obtaining a declaration that the '516 Patent was invalid (and thus risking monetary liability for infringing on the patent).

competition was not the result of any anti-competitive conduct by Zeneca or Barr, but rather the result of the existence of the '516 patent and the decision by the patent holder to enforce it. It is thus not antitrust injury, but rather the result of the legal monopoly that a patent holder possesses. *Cf. Eastman Kodak,* 114 F.3d at 1558 ("The cause of [claimant's] injuries was not that Eastman enforced the [acquired] patent, but that the patent was enforced at all. These injuries, therefore, did not occur 'by reason' of that which made the acquisition allegedly anticompetitive.").

B. Plaintiffs Cannot Allege Antitrust Injury Based on the Settlement Agreement Resuscitating the '516 Patent

Plaintiffs' other claim of injury is essentially that the settlement and *vacatur* deprived other generic manufacturers of the ability to make the legal argument that the *ICI v. Barr* judgment (if affirmed) would collaterally estop Zeneca from claiming the '516 patent was valid in future patent litigation with other ANDA filers. At the time of settlement, however, Barr had no vested right in the judgment still on appeal. *See Asselta v. 149 Madison Ave. Corp.,* 79 F.Supp. 413, 415 (S.D.N.Y.1948) ("A complainant has not any vested right in the decree of the district court while it is subject to review."). If Barr had no such right, it is hard to imagine how other generic manufacturers had legitimate expectations that they could rely upon the judgment on appeal as well. Yet Plaintiffs now seek to base an injury upon the elimination of a judgment on which not even Barr could rely. Plaintiffs point to no case that establishes this result, namely, that forcing other generic

manufacturers to litigate the validity of the '516 patent, is an injury to competition.

It must be noted that in light of the Federal Circuit's later decision in *Novopharm* affirming a district court's decision *upholding* the validity of the '516 patent, plaintiffs' supposition that the Federal Circuit would have affirmed Judge Broderick's decision declaring the '516 patent invalid is also unwarranted. Of course, the *Novopharm* decision could not prevent other generic manufacturers from challenging the patent. *See Ethicon, Inc. v. Quigg,* 849 F.2d 1422, 1429 (Fed.Cir.1988) (Federal Circuit's prior decision upholding patent's validity not binding on another challenge in the courts or the Patent and Trademark Office); *Allen Archery, Inc. v. Browning Mfg. Co.,* 819 F.2d 1087, 1091 (Fed.Cir.1987) (a manufacturer charged with patent infringement will not be collaterally estopped from challenging the validity of the patent as part of its defense to the infringement claim even if the patent's validity was upheld in a prior infringement suit involving a different manufacturer). And when Pharmachemie and Mylan continued their challenges to the validity of the '516 patent even after the *Novopharm* decision, that decision had no impact on the merits of their claims. As noted previously, those challenges failed as well.

Absent any cognizable injury, the Sherman Act claim is dismissed.

III. The Claims for Restitution

Count II alleges that under state common law (*see* Pl. Opp. Mem. at 61) Zeneca has benefitted from unlawfully charging supra-competitive prices, that Barr has benefitted from unlawfully receiving payments from Zeneca and receiving funds from the sales of the licensed tamoxifen to the Plaintiffs, and that therefore equity demands that Defendants disgorge these benefits. (Com pl. ¶¶ 108-115.)

Under the current Draft Restatement, "[a] person who is unjustly enriched at the expense of another is liable in restitution to the other." Restatement (Third) of Restitution & Unjust Enrichment § 1 (Discussion Draft Mar. 31, 2000). Plaintiffs are correct that the state of the common law most likely recognizes unjust enrichment as a source of obligation with its own remedial structure. However, a restitution claim requires that Defendants have "unjustly," *id.*, or "wrongfully" received a benefit. *Geller v. County Line Auto Sales, Inc.*, 86 F.3d 18, 22 (2d Cir.1996).

Plaintiffs' allegations of enrichment focus entirely upon the ability of Zeneca and Barr to charge monopolistic prices for tamoxifen after the Settlement Agreement. As held above, based on plaintiffs' allegations there was nothing impermissible about Zeneca charging monopolistic prices or licensing tamoxifen to Barr. Since whatever benefit received by Zeneca or Barr was not wrongfully secured, no restitution is available. *Id.* ("Because the defendants were not unjustly enriched, a restitution award is not available.") Count II of the Complaint thus is also dismissed.

Appendix B

IV. Plaintiffs' Other State Law Claims

A. Antitrust Claims

Plaintiffs bring state law claims under the antitrust laws of 17 states: Arizona, California, the District of Columbia, Florida, Kansas, Louisiana, Maine, Massachusetts, Michigan, Minnesota, New Jersey, New York, North Carolina, North Dakota, South Dakota, West Virginia, and Wisconsin. Plaintiffs and Defendants agree that state antitrust law should be construed similarly to federal antitrust law where possible.[13] (*See* Def. Consolidated Mem. at 36 and n. 15 (collecting cases and official opinions); Pl. Opp. Mem. at 69 n. 39 (collecting more cases and noting statutory directives).) Accordingly, since Plaintiffs fail to state a claim under the Sherman Act, and since the state antitrust law claims are based on the same allegations, those claims are also dismissed.

B. Unfair Competition and Consumer Protection Laws

Plaintiffs also assert that the Defendants' actions violated consumer protection and unfair competition laws in 21 states: Arizona, California, Florida, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Nevada, New

13. The parties disagree on one point not relevant to the present discussion-whether the *Illinois Brick* rule (prohibiting indirect purchasers from asserting federal antitrust claims) also governs state antitrust law claims where the states in question have not definitively ruled on the issue. Since the allegations otherwise fail to state a claim, this disagreement is immaterial.

Jersey, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Vermont, West Virginia, and Wisconsin.

These state unfair competition laws generally prohibit sellers from engaging in unfairly competitive practices (such as agreements to divide the market) or otherwise making false promises or misrepresentations to the consumer public. Plaintiffs' claims sound wholly in allegations of unfair competition based on the Settlement Agreement that track entirely the allegations underlying the antitrust claims.

However, in order to state a claim under state unfair competition laws related to the enforcement of a patent, "bad faith must be alleged and ultimately proven." *Zenith Electronics Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1355 (Fed.Cir.1999). Otherwise, the claims are preempted by patent law. *Id.* For the reasons already noted, the Complaint fails to allege facts that indicate that Zeneca and Barr acted in bad faith in settling their patent litigation for purposes of federal law. The same result governs the state law claims.

Accordingly, the state unfair competition law claims are also dismissed.

Appendix B

CONCLUSION

For the foregoing reasons, the motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) is granted.

SO ORDERED.

Dated: May 13th, 2003
Brooklyn, New York

s/ I. Leo Glasser
I. Leo Glasser
United States District Judge

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DENYING PETITION FOR REHEARING FILED SEPTEMBER 14, 2006

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Roseann B. MacKechnie
CLERK

Date:	
Docket Number:	03-7641-cv
Short Title:	In Re: Tamoxifen Citrate Antitrust Litigation v.
DC Docket Number:	01-md-1408
DC:	EDNY (BROOKLYN)
DC Judge:	Honorable I. Glasser

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Danie Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 14 day of September two thousand six.

In Re: Tamoxifen Citrate Antitrust Litigation

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC , LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L.-A.G.C. BUILDING TRADES WELFARE FUND, SHEET

Appendix C

METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH & HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Plaintiffs - Appellants

v.

BARR LABS, INC., ASTRAZENECA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Defendants - Appellees.

A petition for panel rehearing and a petition for rehearing en banc having been filed herein by the Plaintiffs-Appellants. Upon consideration by the panel that decided the appeal, it is Ordered that said petition for rehearing is **DENIED**.

It is further noted that the petition for rehearing en banc has been transmitted to the judges for the court in regular active service and to any other judge that heard the appeal and that no such judge has requested that a vote be taken thereon.

For the Court,
Roseann B. MacKechnie, Clerk

By: s/ [illegible]
Motion Staff Attorney

APPENDIX D — DISSENT FROM ORIGINAL OPINION DATED NOVEMBER 2, 2005

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

August Term, 2003

(Argued: July 12, 2004 Decided: November 2, 2005

Docket No. 03-7641

In Re: Tamoxifen Citrate Antitrust Litigation

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L.-A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH & HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Plaintiffs-Appellants,

- v -

BARR LABS. INC., ASTRAZENECA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Defendants-Appellees.

Appendix D

POOLER, *Circuit Judge*:

I respectfully dissent. I believe that the opinion of the court, which dismisses plaintiffs' complaint at the Rule 12(b)(6) stage, shortcuts a process necessary to balance the interests at stake in this litigation. These interests include, on one side, the encouragement of innovation fostered by the patent laws, the public and private interest in amicable settlements, and judicial economy; and, on the other side, an interest in vigorous competition protected by the Sherman Act as well as the interest of consumers in having the validity of a patent litigated. I agree with the majority that balancing is required but differ from them as to (1) the proper balancing analysis, and (2) the ability to perform this analysis without further development of the factual record. In my view, plaintiffs' allegations were sufficient to allow discovery and, thereafter, a more fully informed balancing analysis.

BACKGROUND

I. Plaintiffs' relevant allegations.

Plaintiffs allege that the various agreements described in the majority opinion are a cover for an agreement to allow Zeneca[33] and Barr to monopolize and allocate the tamoxifen market. In support of this proposition, plaintiffs further allege that (1) at the time the two drug manufacturers entered into their agreements, Zeneca's patent had been declared invalid by a district court and Zeneca's appeal was fully briefed

33. Like the majority, I use "Zeneca" to refer collectively to defendants Zeneca, Inc., Astrazeneca Pharmaceuticals LP, and AstraZeneca, Inc. "Barr" refers to defendant Barr Labs, Inc.

before the Federal Circuit; (2) Zeneca agreed to pay Barr $21 million and Barr's supplier $45.4 million in return for Barr's agreement to withdraw its challenge to Zeneca's patent and refrain from entering the generic market until Zeneca's patent expired in 2002; (3) the amount paid to Barr exceeded the amount that Barr could have earned by successfully defending its judgment because the 180-day period during which Barr would have been the only generic manufacturer would have been followed immediately by a highly competitive generic market; (4) although the agreement required Barr to convert its paragraph IV certification to a paragraph III certification, it also provided that Barr could revert to a paragraph IV certification if Zeneca's patent was later declared invalid, which would allow Barr and Zeneca to delay the entry of any subsequent generic challenger into the market; (5) in order to render the agreement effective, Barr was required to join Zeneca in moving for vacatur of the judgment, which motion resulted in the vacatur of the district court's determination that the patent was not valid; (6) subsequent generic challengers faced a thirty-month stay before they could enter the market; (7) Barr did indeed employ its exclusivity period against another generic manufacturer, Mylan Pharmaceuticals, when the latter was poised to enter the market; and (8) the savings to end purchasers who bought the tamoxifen that Barr obtained from Zeneca was only about 5% as compared to the 30% to 80% discount typically available where there is true generic competition.

Appendix D

II. The majority's analysis.

The majority's resolution of this appeal rests on a series of premises. First, the majority states that the Sherman Act aims to encourage competition by prohibiting agreements that unreasonably restrain trade. The majority next states that the patent laws also ultimately aim to stimulate competition and innovation, but that they do so through a system that grants an inventor a time-limited exclusive right in her invention or formulation. These contrasting goals, the majority posits, create a tension in cases where patent and antitrust overlap and require "a delicate balance." *Id.* (quoting *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1067 (11th Cir.2005)).

After thus recognizing the inherent tension between antitrust and patent law, the majority goes on to articulate principles that it believes should be used to resolve this tension in the context of an antitrust challenge to a Hatch-Waxman settlement agreement. First, it notes the general principle that settlements, including patent settlements in the pharmaceutical area, are to be encouraged because they promote the public interest and the interests of the parties. In addition, the majority relies on the Supreme Court's recognition that " 'where there are legitimately conflicting [patent] claims . . . a settlement by agreement rather than litigation, is not precluded by the Sherman Act.' " *Id.* (quoting *Standard Oil Co. v. United States*, 283 U.S. 163, 171, 51 S.Ct. 421, 75 L.Ed. 926 (1931)).

The majority then suggests that rules that severely restrict patent settlements create undue uncertainty concerning

patents and thus might delay the entry of innovative products into the market. It also reasons that, although forcing patent litigation to continue might be pro-competitive in some cases, resolving disputes may also allow the entry into the market of valuable inventions.

Turning to the agreements at issue in this case, the majority states that it cannot find them unreasonable based on the likelihood that Barr would maintain its victory on appeal because courts are ill positioned to predict the outcome of litigation. Puzzlingly, after noting that the validity of a settlement agreement must be judged from the viewpoint of the time in which it was made, the majority relies on the fact that other district courts reached a different conclusion from that of the Southern District of New York to show that it is difficult to assess Barr's likelihood of success on appeal. It finds "of little moment" the fact that the parties reached settlement "after the district court ruled against Zeneca" because all parties have a motivation to eliminate risk on appeal, but finds it significant "[t]hat Zeneca had sufficient confidence in its patent to proceed to trial rather than find some means to settle the case first."

The court concludes "that without alleging something more than the fact that Zeneca settled after it lost to Barr in the district court," plaintiffs have not alleged an antitrust violation. The first "something more" that the majority considers is the $21-million reverse payment Zeneca made to Barr in return for the latter's agreement to stay out of the generic market for tamoxifen and to cooperate in vacating its favorable judgment. It finds no per se bar to reverse payments, indicating that "the fact that the patent holder is

paying to protect its patent monopoly [does not], without more, establish[ ] a Sherman Act violation." The majority also posits that reverse payments are to be expected in the drug patent context because Hatch-Waxman shifted the risk of a lawsuit from an infringer to a patent holder.

Next, after conceding that reverse payments that, like the one alleged here, exceed the profits the generic might expect to make if it prevailed in the underlying litigation look suspicious, the majority holds that such excessive reverse payments are not unlawful, explaining that "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."

The court then articulates its standard for judging whether a Hatch-Waxman settlement agreement violates the antitrust laws: "[A]bsent an extension of the monopoly beyond the patent's scope . . . and absent fraud . . . the question is whether the underlying infringement lawsuit was 'objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.' " *Id.* (quoting *Prof'l Real Estate Investors, Inc. v. Columbia Pictures, Inc.*, 508 U.S. 49, 60, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993)). The majority then holds that plaintiffs did not and cannot-in light of Zeneca's subsequent litigation victories-establish that Zeneca's infringement suit against Barr was objectively baseless.

Appendix D

The majority next considers whether the exclusionary effects of the agreements exceed the patent's scope and concludes that they do not because (1) the agreements did not bar the introduction of any non-infringing products; (2) they ended all litigation between Zeneca and Barr, thus opening the field to other generic challengers; and (3) they did not entirely foreclose competition because they allowed Barr to market Zeneca's version of Tamoxifen. Finally, the majority considers plaintiffs' allegations concerning Barr's manipulation of the exclusivity period. It concludes that although "an agreement to time the deployment of the exclusivity period to extend a patent's monopoly power might well constitute anticompetitive action outside the scope of a valid patent," because the agreements themselves did not exceed the scope of Zeneca's lawful patent, Barr's actions could not be unlawful as in furtherance of an original conspiracy.

The court dismisses as speculative any claim by plaintiffs that Barr and Zeneca entered into a side agreement that Barr would use its exclusivity period in the way it did, claiming that "[a]lthough the Agreement in this case did include a provision allowing Barr to revert its paragraph III certification back to a paragraph IV certification in the event another generic manufacturer successfully invalidated the patent, it seems farfetched, in light of the law at the time, to construe the provision as a conscious and unlawful attempt to manipulate the exclusivity period." The law to which the majority refers is a former federal regulation requiring that in order to obtain an exclusivity period, the generic manufacturer must successfully defend a patent infringement suit. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1065

(D.C.Cir.1998) (citing former 21 C.F.R. 314.107(c)(1)). The majority also argues that Barr's deployment of the exclusionary period is adequately explained "by [its] own interest in protecting itself from competition through a petition to the FDA for a statutorily described benefit" and that nothing in the complaint suggests a conspiracy. Alternatively, the majority suggests that it has grave doubts that the injury plaintiffs allege is antitrust injury because the injury stemmed from the scope of Zeneca's patent and from the inability of other generics to defeat Zeneca's patent.

DISCUSSION

I differ with both the majority's standard for pleading a Hatch-Waxman-settlement antitrust violation and with several subsidiary holdings, conclusions, or assumptions. The requirement that-unless an antitrust plaintiff demonstrates that a settlement agreement exceeds the scope of the patent-it must show that the settled litigation was a sham, i.e., objectively baseless, before the settlement can be considered an antitrust violation is not soundly grounded in Supreme Court precedent and is insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws. Beyond that overarching difference, the majority has, in my view, wrongly (1) accorded dispositive deference to Zeneca's patent rights when its patent had been declared invalid at the time of the settlement; (2) focused on subsequent litigation concerning patent validity rather than the litigation posture at the time of settlement; (3) held that the district court could not assess the likelihood that Zeneca would succeed on appeal; (4) held that plaintiffs insufficiently alleged a conspiracy between

Barr and Zeneca to deploy Barr's paragraph IV certification when it would delay the market entry of another generic manufacturer; and (5) failed to recognize that whether plaintiffs' injuries stem from the alleged Barr/Zeneca conspiracy or from the failure of other generics to invalidate the patent cannot be resolved on the pleadings.

I. The pleading standard.

Relying principally on *Professional Real Estate Investors*, the majority concludes that, in order to attack a Hatch-Waxman settlement on antitrust grounds, plaintiffs must allege either that the agreement gave the patent holder benefits beyond the scope of the patent or that the agreement was a sham, that it was "objectively baseless in the sense that no reasonable litigant would realistically expect success on the merits." Majority op. (quoting 508 U.S. at 60, 113 S.Ct. 1920). I agree that a settlement agreement that confers on the patent holder a greater monopoly benefit than does the patent itself is illegal. However, I do not agree that, absent a showing of benefits exceeding the scope of the patent, the antitrust plaintiff must show that the settled litigation was objectively baseless.

Professional Real Estate Investors is not apposite because it did not involve the settlement of Hatch-Waxman patent litigation. Rather, plaintiffs brought a copyright infringement case, and defendants countersued, alleging that the suit was a sham and a violation of §§ 1 and 2 of the Sherman Act. 508 U.S. at 52, 113 S.Ct. 1920. The district court held that while no infringement occurred, no antitrust violation occurred either because the plaintiffs were entitled

to immunity under *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961), as their litigation "was clearly a legitimate effort and therefore not a sham." 508 U.S. at 53, 113 S.Ct. 1920 (quoting *Columbia Pictures Indus., Inc. v. Prof'l Real Estate Investors, Inc.*, 1990 WL 56166 at * 1 (C.D.Cal.1990)). Both the Court of Appeals and the Supreme Court agreed, and the Supreme Court defined "sham" for the purposes of defeating *Noerr-Pennington* immunity,[34] as the majority does here. *Id.* at 60, 113 S.Ct. 1920. The Court was not called upon to decide and did not decide the standard for pleading an antitrust violation; it simply defined "sham," in a context in which it was already clear that the required standard was sham litigation. It is ill-advised, I think, to import the definition of "sham" used where a party must concededly establish that litigation was "sham" to avoid a well-established immunity from antitrust liability to a context in which we are defining antitrust liability in the first instance. Although Zeneca's original suit was likely protected under the standard set out in *Professional Real Estate Investors*, it does not necessarily follow that the settlement of that suit should be judged on the same grounds.

In fact, other leading cases cited in the majority opinion suggest, although I concede they do not mandate, a contrary conclusion. *See Standard Oil*, 283 U.S. at 180, 51 S.Ct. 421 (noting in the context of upholding cross-licensing

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34. *Noerr-Pennington* immunity derives from both *Noerr* and *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965).

agreements for patents against an antitrust challenge that a "master found, after an elaborate review of the entire art, that the presumption of validity attaching to the patents had not been negatived in any way; that they merited a broad interpretation; that they had been acquired in good faith; and that the scope of the several groups of patents overlapped sufficiently to justify the threats and fears of litigation."); *United States v. Singer Mf'g Co.*, 374 U.S. 174, 197, 83 S.Ct. 1773, 10 L.Ed.2d 823 (1963) (White, *Justice, concurring*) (noting that the majority had not reached issue of whether "collusive termination of a Patent Office interference proceeding pursuant to an agreement between [certain parties] to help one another to secure as broad a patent monopoly as possible, invalidity considerations, notwithstanding" was sufficient, standing alone, to state an antitrust claim and indicating that he believed it was). Both the majority opinion in *Standard Oil* and the concurrence in *Singer* suggest that an antitrust court must go beyond deciding that a lawsuit was not a sham, that is objectively baseless, before it can dismiss an antitrust challenge to the lawsuit's settlement-as opposed to the initiation of the lawsuit-and, in fact, must consider the strength of the patent.

Holding that a Hatch-Waxman settlement agreement cannot violate antitrust laws unless the underlying litigation was a sham also ill serves the public interest in having the validity of patents litigated. *See United States v. Glaxo Group Ltd.*, 410 U.S. 52, 57, 93 S.Ct. 861, 35 L.Ed.2d 104 (1973). This interest exists because "[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be

protected in his monopoly."[35] *Id.* at 58, 93 S.Ct. 861. Litigating the validity of drug company patents is critically important to the general well being in light of the recent trend toward capping the maximum amounts insurers and public benefit plans will spend on medications.

A Hatch-Waxman settlement, by definition, protects the parties' interests as they see them. Whether it also promotes the public's interest depends on the facts. If the validity of the patent is clear, and the generic company receives a license to market the patent holder's product, competition is increased. However, if, as in this case, the patent has already been shown to be vulnerable to attack and the generic manufacturer is paid to keep its generic product off the market, it is hard to see how the public benefits.

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35. The majority suggests, that this interest was adequately protected through the subsequent suits by other generics. I disagree. This position ignores the time gap between the Barr-Zeneca litigation and the subsequent litigation. During this period, had Barr maintained its victory on appeal, which, as I explain below, was quite likely, very ill consumers would have had access to low cost generic tamoxifen. In addition, once Zeneca's patent protection was gone with respect to Zeneca, it was gone with respect to all generic manufacturers, which would have produced a very competitive market at the close of the 180-day exclusivity period. Thus, it was very important to the public interest that Barr and Zeneca allow the appeal to proceed. This does not mean, as the majority suggests that any settlement of patent litigation after the challenger prevails at trial is an antitrust violation. As I discuss below, a Hatch-Waxman settlement agreement, even on appeal from a judgment declaring the patent invalid, is not a per se antitrust violation. Rather, a reviewing court must assess the reasonability of the settlement by weighing various factors including the strength of the patent as it appeared at the time of settlement.

Appendix D

The Hatch-Waxman Act provides an incentive for the second kind of agreement that other patent laws do not provide. Patent litigation other than Hatch-Waxman patent litigation generally proceeds along familiar lines. A patent holder sues an alleged infringer, and the infringer either chooses to go to trial to vindicate its view that the patent is invalid or pays the patent holder money as compensation for damages the patent holder has suffered or as the price of a license. In this context, one can perhaps assume that the parties' relative views on the strength of a patent will result in a pro-competitive or neutral result. If the patent holder believes its patent is strong, it will proceed to trial, knowing that it can collect damages at the end. The generic manufacturer, if it believes the patent holder's patent is weak, may be willing to risk damages and market its product during the litigation, thereby promoting competition. And if the claims are in relative equipoise, a licensing arrangement may well result.

In contrast, a generic competitor subject to Hatch-Waxman cannot enter the market for the first thirty months after litigation is commenced against it. *See* 21 U.S.C. § 355(j)(5)(B)(iii). In addition, whether its attack against the patent is strong or weak, the benefit it will obtain by successfully litigating to the finish is not great. At best, it will obtain 180 days in which it will be the exclusive generic on the market. *See* 21 U.S.C. § 355(j)(5)(B)(iv). On the other hand, the benefits to the public from the completion of litigation can be enormous if the generic challenger prevails as it did, at least initially, here. Once the 180-day exclusivity period is over, any generic that wishes to market a generic product and that can establish its product is bioequivalent to

the patented product can enter the market, thus providing increased competition.

Moreover, the thirty-month stay provides an incentive to the patent holder to pay its generic competitor more than the generic company could have realized from winning the lawsuit. This is so because once the settlement is reached and the litigation dismissed, another generic manufacturer will have to wait at least thirty months after litigation is commenced against it to begin production.[36] Thus, the patent holder will be protected against all generic competition for thirty months after the first lawsuit is terminated. This problem is aggravated when the agreement between the putative competitors provides that the generic company can deploy its exclusivity period after sitting on it until another ANDA applicant attempts to enter the market. These anti-competitive effects—and others not present in this case—have caused antitrust scholars to propose various analytical frameworks for determining whether an antitrust violation has occurred when a patent holder makes a reverse payment to settle patent litigation. The analytical frameworks proposed vary both as to burden of proof and as to the evidence necessary to find a reverse payment illegal.

For instance, Herbert Hovenkamp, Mark Janis, and Mark A. Lemly propose that a Hatch Waxman Act settlement that includes a reverse payment be presumed illegal with the

36. Of course, other generic challengers could file Paragraph IV certifications before the first litigation is resolved, but a second generic manufacturer has little incentive to incur the cost of litigation. Even if it wins, it will have to wait until after the first generic challenger's exclusivity period has expired to market its product.

patent holder being allowed to rebut this presumption "by showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit." Herbert Hovenkamp et al, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L.Rev. 1719, 1759 (2004).

Daniel A. Crane urges a standard somewhat more favorable to the settling parties. *See* Daniel A. Crane, *Ease Over Acuracy in Assessing Patent Settlements*, 88 Minn. L.Rev. 698, 709 (2004) (urging that the dispositive factor should be "the ex ante likelihood that the defendant would be excluded from the market if the case was finally adjudicated"). *Id.* at 709. Because the settling parties will typically have the most documentation relevant to the issue, he contends that "there is relatively little social cost in requiring the settling parties to retain documents going to the core issues in the patent infringement lawsuit." *Id.* However, to avoid unduly chilling patent settlements, Crane, unlike Hovenkamp et al, would not shift the burden of proof to the settling parties. *Id.*

Thomas F. Cotter's approach occupies the middle ground. Cotter would leave on the antitrust defendants the burden of demonstrating the legality of a reverse-payment settlement, but he does not adopt Hovenkamp's position that the reverse payment must be limited to litigation costs. *See* Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley*, 87 Minn. L.Rev. 1789, 1795-97, 1802 (2003). Rather, he

argues that "when the antitrust defendants can show that the payment is below the expected amount of the patent defendant's loss if an injunction were to issue, the burden of proving validity and infringement should be somewhat easier to satisfy than at a full-blown infringement trial." *Id.* at 1814. Cotter rejects, and the other commentators implicitly reject, the approach adopted by the majority. *See id.* at 1811 (noting that requiring antitrust plaintiffs to show that patent litigation is a sham "would permit too many anticompetitive settlements to escape scrutiny. A suit with only a 25% chance of success may not be a sham, but a settlement based upon such a low probability estimate reduces consumer welfare for no apparent offsetting benefit.") (footnote omitted).

Thus, commentators, precedent, and policy suggest the majority's requirement that an antitrust plaintiff show that a Hatch-Waxman lawsuit settled by agreement was a sham-assuming that the agreement did not convey benefits beyond the scope of the patent-is unjustified. A more searching inquiry and a less stringent standard are required to properly protect all interests. I see no reason why the general standard for evaluating an anti-competitive agreement, i.e., its reasonableness, should not govern in this context.[37]

37. The majority argues that applying the general rule of reasonableness would "mak[e] every settlement of patent litigation, at least in the Hatch-Waxman Act context, subject to the inevitable, lengthy and expensive hindsight of a jury as to whether the settlement constituted a 'reasonable' restraint (and, in this case, whether the Federal Circuit would have affirmed or reversed in a patent appeal)" and thus "place a huge damper on such settlements." I doubt that this doomsday scenario would, in fact, take place. Courts would eventually develop rules for judging the reasonableness of a

(Cont'd)

See Clorox. Co. v. Winthrop, Inc., 117 F.3d 50, 56 (2d Cir.1997). In assessing reasonableness, the fact-finder must consider all the circumstances affecting a restrictive agreement. *Id.* Of course, the strength of the patent must be central to any antitrust analysis involving a patent. Thus, in assessing the reasonability of a Hatch-Waxman settlement, I would rely primarily on the strength of the patent as it appeared at the time at which the parties settled and secondarily on (a) the amount the patent holder paid to keep the generic manufacturer from marketing its product, (b) the amount the generic manufacturer stood to earn during its period of exclusivity, and (c) any ancillary anti-competitive effects of the agreement including the presence or absence of a provision allowing the parties to manipulate the generic's exclusivity period. Because plaintiffs allege that the district court's determination of patent invalidity would have been upheld on appeal; that Barr received more than it would have through a victory on appeal; and that Barr and Zeneca agreed that Barr would deploy its paragraph IV certification to defeat other potential generic entrants, I believe that their pleading is adequate.

(Cont'd)

settlement, and as with other litigation, the majority of cases would be resolved in motion practice. Moreover, the majority again emphasizes the acknowledged interest in settlements without acknowledging the absent party in Hatch Waxman litigation settlements, the consumer of medicines. Those consumers have no ability to affect the settlement, which, in some cases, may benefit both parties beyond any expectation they could have from the litigation itself while harming the consumer. There is a panglossian aspect to the majority's tacit assumption that the settling parties will not act to injure the consumer or competition.

Appendix D

II. Ancillary issues.

A. Capacity of the district court to evaluate Zeneca's likelihood of success on appeal.

It appears that the court may have been motivated to adopt the "sham" or objectively baseless standard because it overestimated the difficulty of estimating Zeneca's chance of prevailing on appeal. *See* Majority op. (citing principally *Whitmore v. Arkansas*, 495 U.S. 149, 159-60, 110 S.Ct. 1717, 109 L.Ed.2d 135 (1990), for the proposition that is impossible to predict the likelihood that Barr would have maintained its patent victory on appeal). *Whitmore*, is inapposite; there the Court considered a challenge to one inmate's death sentence from a different inmate, Whitmore, who also had been sentenced to death. 495 U.S. at 153, 110 S.Ct. 1717. Whitmore argued that he had standing because Arkansas's Supreme Court compared the circumstances of any capital case currently before it to prior capital cases to determine whether the death penalty had been arbitrarily applied. *Id.* at 156, 110 S.Ct. 1717. Whitmore claimed that if he obtained federal habeas relief in the future *and* if he were again convicted and sentenced to death *and* appealed to the Arkansas Supreme Court, the failure to include the first inmate's heinous crime in the data base the Arkansas Supreme Court considered would prejudice the review of his sentence. *Id.* at 156-57, 110 S.Ct. 1717. The Court dismissed as speculative the probability of Whitmore's obtaining federal habeas relief, the odds that he would be retried, convicted and sentenced to death once more, and the odds "that the addition of [the first inmate's] crimes to a comparative review 'data base' would lead the Supreme Court of Arkansas to set

aside a death sentence for Whitmore." *Id.* at 157, 110 S.Ct. 1717. To find that the sequence of events Whitmore alleged would actually occur indeed requires multiple layers of speculation. In contrast, by the time of the settlement, Barr had already prevailed at the district court level. The record in that case is presumably available, the standards of review the appellate court would have employed are well known, and it is not outside the bounds of the district court's competence to predict whether Barr would have prevailed on appeal.[38] Judges and juries routinely perform an analogous,

38. The majority also relies on *Boehm v. Comm'r*, 146 F.2d 553 (2d Cir.1945), *aff'd*, 326 U.S. 287, 66 S.Ct. 120, 90 L.Ed. 78 (1945). This case also is strikingly inapposite; the *Boehm* court held only that a taxpayer must claim a loss in the year it becomes obvious and cannot rely on the inherently speculative outcome of litigation seeking to recover some of that loss to justify claiming it in a later year. 146 F.2d at 555. The relevance of that principle to the case at hand is not immediately obvious to me. It is also interesting to note that the Supreme Court affirmed not on the impossibility of predicting litigation outcome but rather because the Tax Court had found that the suit had "no substantial value" and "[t]here was no evidence in the stipulation of the merits of the suit, the probability of recovery or any assurance of collection of an amount sufficient to pay the creditors' claim . . . and to provide a sufficient surplus for stockholders." 326 U.S. at 294, 66 S.Ct. 120. The majority's additional reliance on *Asahi Glass Co. v. Pentech Pharms*, 289 F.Supp.2d 986, 993 (N.D.Il.2003), and *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d. 188, 200-01 (E.D.N.Y.2003), requires little discussion. The statement quoted from *Asahi Glass* that "[n]o one can be *certain* that he will prevail in a patent suit"-is irrelevant to the capacity of skilled corporate counsel and district court judges to evaluate the likelihood that a determination of patent invalidity will be upheld, and the discussion in *Ciprofloxacin* relies primarily on *Whitmore* and *Boehm*, which I have already discussed.

but more difficult, task in legal malpractice cases in which they must estimate whether, absent attorney error, a party would have prevailed at trial. Estimating the possibility of success on appeal with the assistance of the full record and the parties' briefs is much simpler. Certainly the review would not be so difficult as to justify a sham litigation test.

B. The strength of Zeneca's patent.

As the majority states, the reasonableness of agreements under antitrust law must be judged by the circumstances existing at the time when the agreements were made . *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1207 (2d Cir.1981) ("Because the essence of a patent is the monopoly or exclusionary power it confers upon the holder; analyzing the lawfulness of the acquisition of the patent [within an antitrust analysis] necessitates that we primarily focus upon the circumstances of the acquiring party and the status of the relevant product and geographic markets at the time of acquisition."). When the agreements here were reached, Judge Broderick had found by clear and convincing evidence that Zeneca's patent was invalid. Therefore, the patent could no longer be considered presumptively valid. *See Shelcore, Inc. v. Durham Indus., Inc.*, 745 F.2d 621, 624-25 (Fed.Cir.1984) ("The presumption of validity does not guide our analysis on appeal. Rather, we review the findings and conclusions of a district court under the appropriate standard of review.")

The majority, citing *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1377-78 (Fed.Cir.2002), appears to suggest that *Shelcore* is no longer good law and that patents are presumed

valid on appeal even if they have been declared invalid by the district court. I respectfully suggest that the majority places too much weight on *Rosco*. The *Rosco* court simply reiterated the statutory language indicating that patents are presumed valid. 304 F.3d at 1377. It then held that the district court had improperly found that plaintiffs produced clear and convincing evidence to overcome this presumption and thus reversed its finding of validity as to one patent. *Id.* at 1378-79. This analysis is a far cry from a statement that a patent must be presumed valid on appeal because the latter holding would imply-contrary to *Shelcore* and Federal Rule of Civil Procedure 52(a)-that the district court's factual findings in support of its ultimate conclusion of invalidity are entitled to no deference.

Alternatively the majority suggests that it is not important where the presumption of validity lay at the moment of appeal because the patent holder was still entitled to protect its monopoly. However, even assuming, contrary to my view, that most patent settlements should be subject to the "sham litigation" standard, surely there are strong policy reasons for applying more searching scrutiny where a court of competent jurisdiction has found the patent to be invalid.

C. The majority's reliance on Zeneca's subsequent litigation victories.

The majority also focuses on the subsequent litigation between other generics and Zeneca to demonstrate that plaintiffs cannot support a claim that Zeneca's litigation against Barr was sham litigation. Of course, in my view, plaintiffs need not plead or prove sham or objectively baseless

litigation. But, in addition, the majority's discussion of the later litigation appears to violate its own acknowledgment of the basic principle that "the reasonableness of agreements under the antitrust laws are to be judged at the time they are entered into." Majority op. (quoting *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1306 (11th Cir.2003) (citing, *inter alia*, *SCM Corp.*, 645 F.2d at 1207)). At the time Zeneca and Barr settled the appeal, the existing facts made it fairly likely, if not certain, that Barr would prevail. Judge Broderick had judged the credibility of the witnesses and found that Zeneca willfully withheld information from the FDA. That finding is quintessentially factual. Thus, the Federal Circuit could have set it aside only for clear error. Fed.R.Civ.P. 52(a). Without the record, I cannot say that the Federal Circuit would have been required to affirm, but, as I am sure the majority will concede, it is the rare case in which an appellate court sets aside a trial court's credibility findings.[39] Had Barr prevailed, on appeal, as I expect it would have, Zeneca would have been estopped from asserting the validity of its patent in any subsequent litigation. Therefore, there is a certain unfairness in using the subsequent litigation, which would not have existed had Barr prevailed on appeal, to demonstrate that plaintiffs cannot establish that Barr would have prevailed on appeal.[40]

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39. I do not find persuasive the statistics the majority cites on the frequency of reversal in the Federal Circuit. These statistics would include decisions construing the patent and making other legal determinations. Therefore, they do nothing to show how frequently the Federal Circuit reverses credibility determinations on appeal.

40. I recognize that it makes more sense to use the subsequent litigation to argue that plaintiffs could not prove the Zeneca lawsuit was not a sham. However, as noted, I do not believe this is an appropriate test.

Appendix D

D. Conspiracy to use Barr's paragraph IV certification in an anticompetitive manner.

I turn now to the majority's expressed belief that the complaint cannot be read to plausibly allege a conspiracy between Barr and Zeneca to deploy Barr's putative exclusivity period to their joint benefit and to the detriment of other potential competitors and consumers. A complaint need "include only 'a short and plain statement of the claim showing the pleader is entitled to relief.' " *Swierkiewicz v. Sorema*, 534 U.S. 506, 512, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002) (quoting Fed.R.Civ.P. 8(a)(2)). A simplified notice pleading standard is acceptable because "liberal discovery rules and summary judgment motions" allow the parties "to define disputed facts and issues and to dispose of unmeritorious claims." *Id.* The majority requires more than *Swierkiewicz* mandates when it complains of plaintiffs' failure to plead evidentiary facts that create an inference of conspiracy.

The court additionally attacks the plausibility of plaintiffs' allegations because, at the time Barr and Zeneca entered into their agreements, a generic enjoyed the benefit of the exclusivity period only if it had successfully defended an infringement lawsuit. *See Mova Pharm.*, 140 F.3d at 1065 (citing former 21 C.F.R. § 314.107(c)(1)). This regulation was struck down after the agreements at issue. *See id.* at 1076. Because the regulation was in effect when Barr and Zeneca finalized their agreement, the majority finds it implausible that they could have envisioned any anti-competitive effect from the portion of the agreement allowing Barr to deploy its exclusivity period if another generic manufacturer

succeeded in invalidated Zeneca's patent. That inference is certainly one that a reasonable fact finder could draw from the facts alleged to date. However, a reasonable fact-finder could also conclude that it is quite unlikely that sophisticated parties would include in their agreement a provision that had no potential benefit to either of them. Is it not at least as likely that the parties were conscious that the regulation was vulnerable to attack and that they wished to add another layer of protection against potential competitors in the event the regulation was invalidated? Discovery would presumably produce materials relevant to determining whether this provision was part of an antitrust conspiracy between Barr and Zeneca. Among other things, the parties may have had written communications concerning the purpose of the exclusionary-period clause. If not, the corporate employees who negotiated the agreement could be deposed. And, the parties could explore the state of legal discussion concerning the successful-defense requirement at the time of the agreement. Thus, it is premature to reject out of hand plaintiffs' claim that Barr and Zeneca agreed to the exclusivity-period provision because they wanted to further restrict other generic manufacturers' ability to market Tamoxifen.

E. Antitrust injury.

In addition to affirming dismissal of the paragraph IV certification claim because plaintiffs did not adequately describe an antitrust violation, the majority states that it has "grave doubt as to whether, even if the defendants agreed to deploy the exclusionary period to protect their shared monopoly power, the injury that the defendants allege they

suffered in this regard constitutes 'antitrust injury.' " The majority's doubt stems, in part, from Zeneca's victories in subsequent patent litigation. Because these victories could not have existed if (1) the settlement agreement had not been signed and (2) Barr had prevailed on appeal, they are not finally determinative of causation. Therefore, it is necessary to assess the strength of Zeneca's patent in order to decide whether the injuries were really caused by the patent itself or by the agreements.

III. The inappropriateness of dismissal at the Rule 12(b)(6) stage.

Applying the reasonableness inquiry that I suggest requires a factual record not yet in existence. We have no sense of the value to Barr of the exclusivity period it gave up or the relationship of the value of this period to the reverse payment Zeneca made. Nor do we have any sense of the negotiations between the parties concerning the provision that allowed Barr to revivify its Paragraph IV certification. Finally no judge or appellate panel has attempted to discern whether Judge Broderick's findings of facts were clearly erroneous. Allowing the parties to develop a record and make summary judgment motions would give the district court information it needs to assess the reasonableness of the agreements.

However, even under the majority's newly articulated standard, I believe that it was wrong to affirm the dismissal. At a minimum, the plaintiffs should be allowed to develop a factual record to demonstrate that Zeneca's litigation was sham because they had no reason to anticipate the standard

articulated here. I note that the courts that have finally rejected antitrust challenges to Hatch-Waxman settlements have done so after reviewing a full record. *See Schering-Plough*, 402 F.3d at 1058 (granting a petition for review of and reversing an agency decision made upon a full record that granted injunctive relief against certain Hatch-Waxman settlements); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F.Supp.2d 514, 517 (E.D.N.Y.2005) (granting summary judgment motion).

CONCLUSION

Because I disagree with the majority's test for judging whether a Hatch-Waxman agreement violates antitrust law, and because I believe it was inappropriate to dismiss plaintiffs' complaint without allowing discovery, I respectfully dissent.

APPENDIX E — PERTINENT TEXT OF RELEVANT STATUTES

SHERMAN ANTITRUST ACT

Section 1: Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 1.

Section 2: Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 2.

Appendix E

DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 ("HATCH-WAXMAN ACT"), AS AMENDED

* * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

* * *

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

* * *

(B) Notice of opinion that patent is invalid or will not be infringed

(i) *Agreement to give notice.* An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) *Timing of notice.* An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

Appendix E

(iii) *Recipients of notice.* An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) *Contents of notice.* A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

* * *

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary

and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III). (iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order

because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—(aa) the date on which the court enters judgment reflecting the decision; or (bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or (bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II). In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) *180-day exclusivity period*

(I) *Effectiveness of application.* Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

Appendix E

(II) *Definitions.* In this paragraph:

(aa) *180-day exclusivity period.* The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) *First applicant.* As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) *Substantially complete application.* As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) *Tentative approval*

(AA) *In general*

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there

is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) *Limitation*

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) *Civil action to obtain patent certainty*

(i) *Declaratory judgment absent infringement action*

(I) *In general*

No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) *Filing of civil action*

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) *Offer of confidential access to application*

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to

persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) *Counterclaim to infringement action*

(I) *In general*

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent

information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) *No independent cause of action*

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) *No damages.* An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) *Forfeiture of 180-day exclusivity period*

(i) *Definition of forfeiture event.* In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) *Failure to market.* The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

Appendix E

(II) *Withdrawal of application.* The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) *Amendment of certification.* The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) *Failure to obtain tentative approval.* The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) *Agreement with another applicant, the listed drug application holder, or a patent owner.* The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

Appendix E

(VI) *Expiration of all patents.* All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) *Forfeiture.* The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) *Subsequent applicant.* If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

Appendix E

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the

thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

* * *

21 U.S.C. §355(j).

(June 25, 1938, c. 675, § 505, 52 Stat. 1052; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; June 25, 1948, c. 646, § 32(b), 62 Stat. 991; May 24, 1949, c. 139, § 127, 63 Stat. 107; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; June 11, 1960, Pub.L. 86-507, § 1(18), 74 Stat. 201; Oct. 10, 1962, Pub.L. 87- 781, Title I, §§ 102(b) to (d), 103(a), (b), 104(a) to (d)(2), 76 Stat. 781- 783, 784, 785; Aug. 16, 1972, Pub.L. 92-387, § 4(d), 86 Stat. 562; Sept. 24, 1984, Pub.L. 98-417, Title I, §§ 101, 102(a) to (b)(5), 103, 104, 98 Stat. 1585, 1592, 1593, 1597; May 13, 1992, Pub.L. 102-282, § 5, 106 Stat. 161; Aug. 13, 1993, Pub.L. 103-80, § 3(n), 107 Stat. 777; Nov. 21, 1997, Pub.L. 105-115, Title I, §§ 115(a), (b), 117, 119, 120, 124(a), 111 Stat. 2313, 2315, 2316, 2318, 2324; Nov. 29, 1999, Pub.L. 106-113, Div. B, § 1000(a)(9)

Appendix E

[Title IV, § 4732(b)(11)], 113 Stat. 1536, 1501A-584; Jan. 4, 2002, Pub.L. 107-109, § 15(c)(1), 115 Stat. 1420; Dec. 3, 2003, Pub.L. 108-155, § 2(b)(1), 117 Stat. 1941; Dec. 8, 2003, Pub.L. 108-173, Title XI, §§ 1101(a), (b), 1102(a), 1103(a), 117 Stat. 2448, 2452, 2457, 2460.)

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

SEC. 1112. NOTIFICATION OF AGREEMENTS.

(a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and a brand name drug company that enter into an agreement described in paragraph (2) shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between a generic drug applicant and a brand name drug company is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the listed drug in the ANDA involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) AGREEMENT WITH ANOTHER GENERIC DRUG APPLICANT.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the generic drugs for which such ANDAs were submitted.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between two generic drug applicants is an agreement regarding the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to the ANDAs with which the agreement is concerned.

(c) FILING—

Appendix E

(1) AGREEMENT.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that such parties are not required to file an agreement that solely concerns

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any agreements between the parties that are not described in such subsections and are contingent upon, provide a contingent condition for, or are otherwise related to an agreement that is required in subsection (a) or (b) to be filed in accordance with this subsection.

(3) DESCRIPTION.—In the event that any agreement required in subsection (a) or (b) to be filed in accordance with this subsection has not been reduced to text, each of the parties involved shall file written descriptions of such agreement that are sufficient to disclose all the terms and conditions of the agreement.

Appendix E

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003).